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(54) Title: A SOLID-STATE LASER CRYSTAL ASSEMBLY

(57) Abstract: A solid-state laser crystal assembly is provided, comprising a solid-state laser crystal for emission of a laser beam, a cooling member for dissipation of heat generated by the laser and having a cooling surface, the solid-state laser crystal being positioned adjacent to the cooling surface, and a holder for holding the cooling member and the solid-state laser crystal so that the solid-state laser crystal is in heat dissipating contact with the cooling surface. The solid-state laser crystal is, thus, removably positioned at the cooling surface of the cooling member and is, during operation of the assembly, held in this position by the holder. The laser crystal assembly may further comprise a first transparent thermally conductive member being positioned between the cooling surface and the solid-state laser crystal. The first transparent conductive member may for example be made of sapphire.



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A SOLID-STATE LASER CRYSTAL ASSEMBLY

FIELD OF THE INVENTION

- 5 The present invention relates to a solid-state laser crystal assembly facilitating cooling of a solid-state laser crystal during emission of light.

BACKGROUND OF THE INVENTION

- 10 In US 5,553,088 a solid-state laser crystal assembly is disclosed with a solid-state disc laser that is pumped with a pumping light source. The solid-state laser crystal is positioned at a cooling surface of a cooling member for dissipation of heat generated in the solid-state laser crystal. The cooling member forms a carrier for the solid-state laser crystal. The radiated laser beam propagates approximately parallel to the temperature
15 gradient in the laser. Due to heat dissipation into the cooling member, the assembly facilitates pumping of the laser with a high pumping power. Further, since the radiated laser beam propagates approximately parallel to the temperature gradient in the solid body, the beam is exposed to the same temperature gradient in all cross-sectional areas. Thus, the temperature gradient does not lead to an adverse effect on the beam quality at
20 a high pumping power.

In order to obtain an effective thermal coupling of the solid-state laser crystal to the cooling member, the solid-state laser crystal may be provided with a metal layer, preferably of copper, which is connected via a contact layer made of soft metal, preferably
25 of soft solder or indium, with the cooling surface of the cooling member.

It is an important disadvantage of the known assembly that the solid-state laser crystal has to be secured to the cooling member, e.g. by gluing, soldering, or cold-welding. All of these attachment methods require that surfaces to be securely attached to each other are
30 high quality surfaces, i.e. clean, plane and highly polished surfaces. Further, the attachment methods stress the attached parts mechanically and soldering also stresses soldered parts thermally.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a solid-state laser crystal assembly without the above-mentioned disadvantages.

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It is a further object of the present invention to provide a solid-state laser crystal assembly that is easy to disassemble, e.g. for servicing purposes, cheap, and easy to manufacture.

According to a first aspect of the present invention, the above-mentioned objects are
10 fulfilled by a solid-state laser crystal assembly comprising a solid-state laser crystal for emission of a laser beam, a cooling member for dissipation of heat generated by the laser and having a cooling surface, the solid-state laser crystal being positioned adjacent to the cooling surface, and a holder for holding the cooling member and the solid-state laser crystal so that the solid-state laser crystal is in heat dissipating contact with the cooling
15 surface.

According to a second aspect of the present invention, the above-mentioned objects are fulfilled by a method of producing a solid-state laser crystal assembly comprising the steps of positioning a solid-state laser crystal for emission of a laser beam adjacent to a
20 cooling surface of a cooling member for dissipation of heat generated by the laser, and mounting the cooling member and the solid-state laser crystal with a holder so that the solid-state laser crystal is in heat dissipating contact with the cooling surface.

It is an important advantage of the present invention that the solid-state laser crystal is not
25 secured to the cooling member by gluing, soldering, cold-welding, etc. Instead, the solid-state laser crystal is removably positioned at the cooling surface of the cooling member and, during operation of the assembly, is held in this position by the holder. Thus, the requirement of tedious and time consuming working of surfaces of the solid-state laser crystal and the cooling member, respectively, in order to obtain high quality surfaces that
30 may be reliably secured to each other is hereby avoided and thus, manufacture of the solid-state laser crystal assembly is greatly simplified.

Further the assembly may be disassembled, e.g. for exchange of a defect solid-state laser crystal, facilitating service and repair.

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The assembly may comprise a thermally conductive compound that is positioned between the solid-state laser crystal and the cooling member for decreasing the thermal resistance between the solid-state laser crystal and the cooling member.

- 5 Preferably, the thickness of the layer of thermally conductive compound ranges from 50 μ to 100 μ .

In a preferred embodiment, the solid-state laser crystal may comprise a reflective coating on the surface facing the cooling member.

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The holder may comprise an upper member and a base member, the solid-state laser crystal and the cooling member being held between the upper member and the base member.

- 15 In order to reduce the thermal resistance between the solid-state laser crystal and ambient, the base member may contain flow channels for a cooling liquid for absorption and removal of heat conducted through the cooling member to the base member.

- The thermal resistance may be further reduced by positioning of a heat pump, such as a
20 thermally conductive element, a peltier element, etc, between the cooling member and the base part for increased transportation of heat from the cooling member to the base part.

Preferably, the cooling member is made of thermally conductive material, such as copper, CVD diamond, etc.

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To further increase the dissipation of heat generated in the solid-state laser crystal, the solid-state laser crystal assembly may further comprise a first transparent thermally conductive member being positioned between the cooling surface and the solid-state laser crystal. Preferably, the thermally conductive member is made of a material

- 30 transparent to the laser beam emitted from the solid-state laser crystal. The thermally conductive member may, for example, be made of sapphire. In a preferred embodiment of the invention the thermally conductive member is bonded to the solid-state laser crystal, for example by anodic bonding of the thermally conductive member to the solid-state laser crystal. The thermally conductive compound then being positioned between the cooling
35 member and the first transparent thermally conductive member.

The cooling member may comprise a transparent opening, the transparent opening being adapted to transmit the laser beam emitted from the solid-state laser crystal. In a preferred embodiment the transparent opening is a boring through the cooling member.

- 5 Hereby, the heat generated in the solid-state laser crystal may be dissipated through the first transparent thermally conductive member to the cooling surface surrounding the boring through the cooling member.

- The solid-state laser crystal may thus be adapted to emit the laser beam through the
10 transparent opening, facilitating mounting of the solid-state laser crystal anywhere in the laser cavity and thus not necessarily as an active end mirror.

- To still further increase the dissipation of heat generated in the solid-state laser crystal, the solid-state laser crystal assembly may further comprise a second transparent
15 thermally conductive member being positioned on an opposite site of the laser crystal in relation to the first thermally conductive member. Hereby, the heat generated in the solid-state laser crystal may be transmitted in both directions in relation to the longitudinal direction of the solid-state laser crystal. The first and the second transparent thermally conductive members may be connected or in thermally conductive contact at areas of the
20 members extending beyond the solid-state laser crystal

- The second transparent thermally conductive member may be bonded to the opposite site of the solid-state laser crystal in relation to the first thermally conductive member, for example by anodic bonding.
25

- Pumping light may enter the solid-state laser crystal at any angle in relation to its surfaces. In the preferred embodiment, the solid-state laser crystal is a disc laser having the shape of a thin circular plate with an upper surface and a lower surface. When the solid-state laser crystal is positioned in the assembly, the lower surface faces the cooling
30 member and the output laser beam is emitted from the upper surface along a propagation axis that is substantially perpendicular to the upper surface. Preferably, pumping light is emitted towards the upper surface of the solid-state laser crystal at an obtuse angle in relation to the upper surface.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a cut-away cross-sectional view of a solid-state laser crystal assembly according to the present invention,

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Fig. 2 shows a solid-state laser crystal assembly according to the present invention, and

Fig. 3 shows a solid-state laser crystal assembly comprising a transparent thermally conductive member.

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DESCRIPTION OF A PREFERRED EMBODIMENT

Figs. 1 and 2 show in perspective a solid-state laser crystal assembly 10 according to the present invention. The solid-state laser crystal assembly 10 comprises a solid-state laser
15 crystal 12 for emission of a laser beam 14, and a cooling member 16 for dissipation of heat generated by the solid-state laser crystal 12 and having a cooling surface 18. The solid-state laser crystal 12 is positioned adjacent to the cooling surface 18. The assembly 10 also has a holder 20 for holding the cooling member 16 and the solid-state laser crystal 12 so that the solid-state laser crystal 12 is in heat dissipating contact with the cooling
20 surface 18.

A thermally conductive compound 22 is positioned between the solid-state laser crystal 12 and the cooling member 16 for decreasing the thermal resistance between the solid-state laser crystal 12 and the cooling member 16. Preferably, the thickness of the layer of
25 thermally conductive compound ranges from 50 μ to 100 μ .

The holder 20 may comprise an upper member 24 and a base member 26, the solid-state laser crystal 12 and the cooling member 16 being held between the upper member 24 and the base member 26 that are kept together by fastening means, such as screws 34.

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In order to reduce the thermal resistance between the solid-state laser crystal 12 and ambient, the base member 26 may contain flow channels 28 for a cooling liquid for absorption and removal of heat conducted through the cooling member 16 to the base member 26.

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The thermal resistance may be further reduced by positioning of a heat pump 30, such as a thermally conductive element, a peltier element, etc, between the cooling member 16 and the base part 26 for increased transportation of heat from the cooling member 16 to the base part 26.

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Pumping light 32 is emitted towards the upper surface of the solid-state laser crystal 12 at an obtuse angle in relation to the upper surface.

Fig. 3 shows a solid-state laser assembly according to an embodiment of the invention. A first transparent thermally conductive member 36 is positioned adjacent the cooling surface 18 of the cooling member 16, and the solid-state laser crystal is then positioned adjacent to the first transparent thermally conductive member 36, on an opposite side. The first transparent thermally conductive member is made of sapphire, but also any other thermally conductive material transparent for the laser beam emitted by the solid-state laser crystal 12 may be used. The first transparent thermally conductive member 36 is bonded to the solid-state laser crystal 12 by anodic bonding so that an optically clean connection is obtained.

The indentations 40 are adapted to receive at least part of the screws 34 (shown in Fig. 2).

A second transparent thermally conductive member (not shown) may be positioned adjacent to the solid-state laser crystal 12 on the side of the solid-state laser crystal opposite the first transparent thermally conductive member so that heat generated by the solid-state laser crystal may be dissipated in the transparent thermally conductive members and thus conducted away from the solid-state laser crystal in both lengthways directions of the laser rod. The solid-state laser crystal is thus positioned in-between two transparent thermally conductive members in a sandwich-like structure. The second transparent thermally conductive member may be bonded to the solid-state laser crystal.

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The cooling member 16 has a boring 38, so that a laser beam (not shown) emitted from the solid-state laser 12 may be transmitted through the first transparent thermally conductive member and through the boring 38 of the cooling member 16. Hereby, the laser crystal may be positioned anywhere in a laser cavity (not shown) facilitating emission of light from/incident light at both ends of the laser rod.

35

When the cooling member has a boring, the effective cooling area of a solid-state laser crystal 12 positioned adjacent the cooling surface 18 is reduced by the sectional area of the boring. To compensate for the reduced cooling area, the transparent thermally
5 conductive member is positioned so that at least a part of the transparent thermally conductive member is positioned adjacent to the cooling surface 18. The heat is thus dissipated in the transparent thermally conductive member and lead to the cooling member 18. The heat transport in the transparent thermally conductive member is then horizontal but this has only a limited effect on the vertical heat dissipation in the solid-state
10 laser crystal so that no 'thermal lens' effect is seen in the solid-state laser crystal.

The first transparent thermally conductive member 36 is in Fig. 3 shown having a circular disc form, but it is envisaged that the first and second transparent thermally conductive members may obtain any form suitable for being thermally connected to the solid-state
15 laser crystal for cooling the laser crystal.

CLAIMS

1. A solid-state laser crystal assembly comprising
 - 5 a solid-state laser crystal for emission of a laser beam,

a cooling member for dissipation of heat generated by the laser and having a cooling surface, the solid-state laser crystal being positioned adjacent to the cooling surface, and
 - 10 a holder for holding the cooling member and the solid-state laser crystal so that the solid-state laser crystal is in heat dissipating contact with the cooling surface.
2. A solid-state laser crystal assembly according to claim 1, wherein the holder further comprises an upper member and a base member, the solid-state laser crystal and the
 - 15 cooling member being held between the upper member and the base member.
3. A solid-state laser crystal assembly according to claim 2, wherein the base member contains flow channels for a cooling liquid.
- 20 4. A solid-state laser crystal assembly according to claims 2 or 3, further comprising a heat pump positioned between the cooling member and the base part for increased transportation of heat from the cooling member to the base part.
5. A solid-state laser crystal assembly according to claim 4, wherein the heat pump is a
 - 25 thermally conductive element.
6. A solid-state laser crystal assembly according to claim 5, wherein the heat pump is a peltier element.
- 30 7. A solid-state laser crystal assembly according to any of the preceding claims, further comprising a thermally conductive compound positioned between the solid-state laser crystal and the cooling member.
8. A solid-state laser crystal assembly according to any of the preceding claims, wherein
 - 35 the cooling member is made of copper.

9. A solid-state laser crystal assembly according to any of the preceding claims, wherein the solid-state laser crystal assembly further comprises a first transparent thermally conductive member, the first transparent thermally conductive member being positioned between the cooling surface and the solid-state laser crystal.

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10. A solid-state laser crystal assembly according to claim 9, wherein the first transparent thermally conductive member is bonded to the solid-state laser crystal.

11. A solid-state laser crystal assembly according to claims 9 or 10, wherein the cooling
10 member comprises a transparent opening, the transparent opening being adapted to transmit the laser beam emitted from the solid-state laser crystal.

12. A solid-state laser crystal assembly according to claim 11, wherein the solid-state laser crystal is adapted to emit the laser beam through the transparent opening.

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13. A solid-state laser crystal assembly according to any of claims 9-12, further comprising a second transparent thermally conductive member being positioned on an opposite site of the solid-state laser crystal in relation to the first thermally conductive member.

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14. A solid-state laser crystal assembly according to claim 13, wherein the second transparent thermally conductive member is bonded to the solid-state laser crystal.

15. A method of producing a solid-state laser crystal assembly comprising the steps of:
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positioning a solid-state laser crystal for emission of a laser beam adjacent to a cooling surface of a cooling member for dissipation of heat generated by the laser, and

holding the cooling member and the solid-state laser crystal with a holder so that the
30 solid-state laser crystal is in heat dissipating contact with the cooling surface.

16. A method according to claim 15, further comprising the steps of
- providing a holder with an upper member and a base member, and
- 5 positioning the solid-state laser crystal and the cooling member between the upper member and the base member.
17. A method according to claim 16, further comprising the step of providing the base member with flow channels for a cooling liquid.
- 10
18. A method according to claims 16 or 17, further comprising the step of positioning a heat pump between the cooling member and the base part for increased transportation of heat from the cooling member to the base part.
- 15 19. A method according to claim 18, wherein the heat pump is a thermally conductive element.
20. A method according to claim 19, wherein the heat pump is a peltier element.
- 20 21. A method according to any of claims 15-20, further comprising the step of positioning a thermally conductive compound between the solid-state laser crystal and the cooling member.
22. A method according to any of claims 15-21, further comprising the step of providing a
- 25 cooling member made out of copper.
23. A method according to any of claims 15-22, further comprising the step of positioning a first transparent thermally conductive member between the cooling surface and the solid-state laser crystal.
- 30
24. A method according to claim 23, further comprising the step of bonding the first transparent thermally conductive member to the solid-state laser crystal.

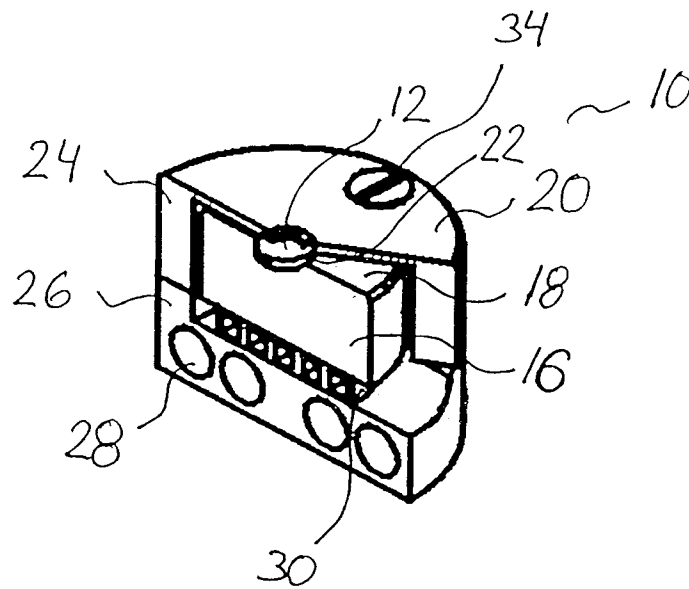
25. A method according to claims 23 or 24, further comprising the step of providing a transparent opening in the cooling member, the transparent opening being adapted to transmit the laser beam emitted from the solid-state laser crystal.

5 26. A method according to claim 25, wherein the solid-state laser crystal is adapted to emit the laser beam through the transparent opening.

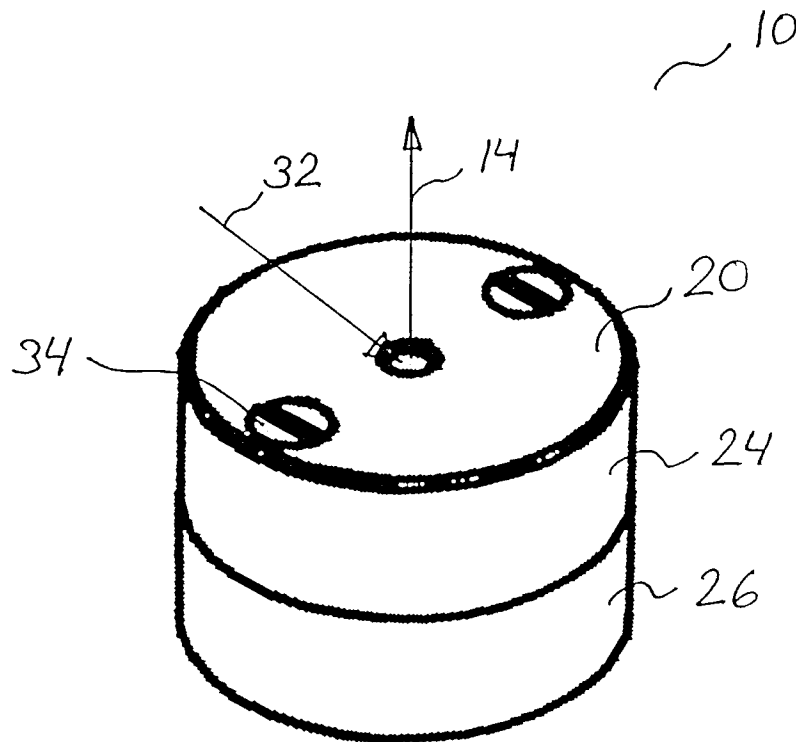
27. A method according to any of claims 23-26, further comprising the step of positioning a second transparent thermally conductive member on an opposite site of the solid-state
10 laser crystal in relation to the first thermally conductive member.

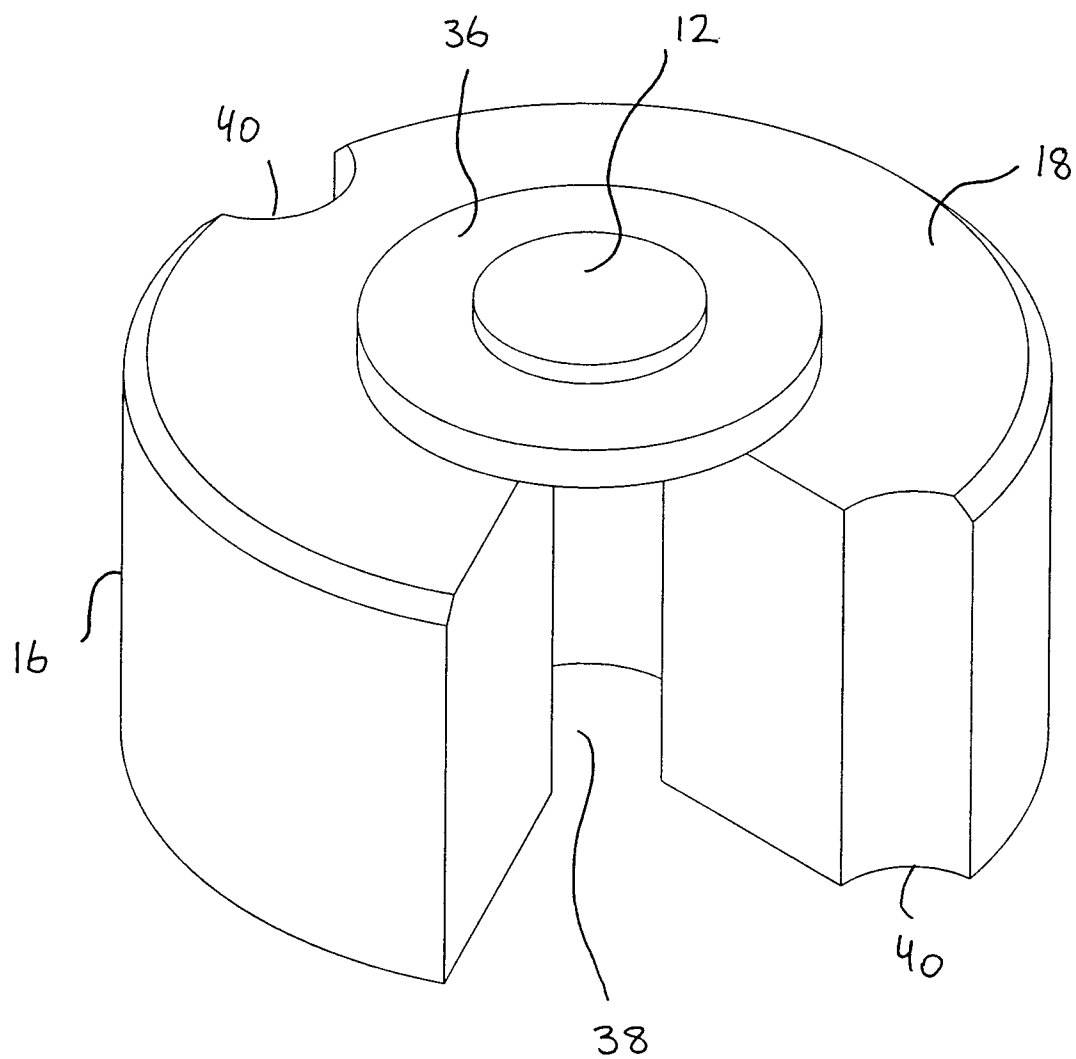
28. A method according to claim 27, further comprising the step of bonding the second transparent thermally conductive member to the solid-state laser crystal.

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**Fig. 1**

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**Fig. 2**

3/3**Fig. 3**

INTERNATIONAL SEARCH REPORT

Int'l Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 H01S3/042

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 H01S

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 10494 A (SPIELMANN CHRISTIAN ;KRAUSZ FERENC (AT); STINGL ANDREAS (AT)) 12 March 1998 (1998-03-12) abstract page 10, line 14 -page 11, line 12 ---	1,2,8, 15,16
X	WO 99 27621 A (KRAUSZ FERENC ;STINGL ANDREAS (AT); FEMTOLASERS PRODUKTIONS GMBH () 3 June 1999 (1999-06-03) the whole document ---	1-7, 15-20
A	DE 41 32 063 A (DEUTSCHE AEROSPACE) 8 April 1993 (1993-04-08) figure 7 ----- -/--	1,9-14

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "&" document member of the same patent family

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 553 088 A (BRAUCH UWE ET AL) 3 September 1996 (1996-09-03) cited in the application abstract; figures 2,3 -----	1,3,8,9
A	US 5 581 569 A (TANUMA RYOHEI) 3 December 1996 (1996-12-03) column 4, line 50 - line 55 column 5, line 8 - line 11 -----	1-3
A	US 5 907 570 A (CHENG EMILY ET AL) 25 May 1999 (1999-05-25) figure 3 -----	1,8
A	US 5 331 507 A (KYUNG JOHNNY S ET AL) 19 July 1994 (1994-07-19) column 1, line 21 - line 27; claim 1 -----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 00/00356

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9810494 A	12-03-1998	AT 405992 B AT 158296 A EP 0923797 A	25-01-2000 15-05-1999 23-06-1999
WO 9927621 A	03-06-1999	AT 405776 B AT 199297 A AU 9615598 A EP 1034584 A	25-11-1999 15-03-1999 15-06-1999 13-09-2000
DE 4132063 A	08-04-1993	NONE	
US 5553088 A	03-09-1996	DE 4344227 A DE 59407111 D EP 0632551 A EP 0869591 A EP 0869592 A	19-01-1995 26-11-1998 04-01-1995 07-10-1998 07-10-1998
US 5581569 A	03-12-1996	JP 7283470 A	27-10-1995
US 5907570 A	25-05-1999	EP 1025624 A WO 9921250 A	09-08-2000 29-04-1999
US 5331507 A	19-07-1994	NONE	

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DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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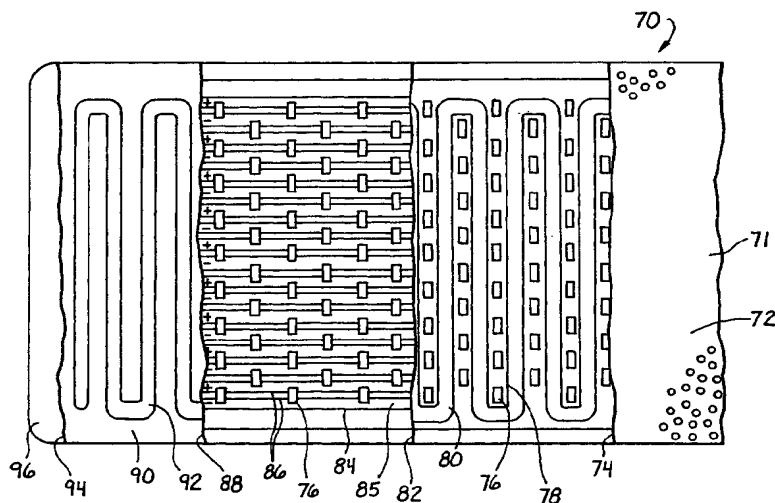
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— With amended claims.

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(54) Title: FLEXIBLE ILLUMINATORS FOR PHOTOTHERAPY



(57) Abstract: A flexible illuminator (30) for external phototherapy is disclosed having at least one light generating source (76), preferably a plurality of light generating sources, on a flexible substrate (84). The flexible substrate may be a printed circuit board, and the light generating sources may be surface mount LEDs. Structure for diffusing light (111) from the discrete light sources, and/or a system for transferring heat away from a skin contact surface are provided. The illuminator may be formed as a pad (64) to be wrapped around an infant or a limb of an adult, or as a mat (60). The illuminator may be passively or actively cooled so that the skin contact surface remains below the desired temperature. The LED is preferably blue or green, and an ultraviolet filter (110) may be provided.



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FLEXIBLE ILLUMINATORS FOR PHOTOTHERAPY**Field of the Invention**

The present invention pertains to devices and methods of external phototherapy and, in particular, to phototherapy devices for use in close proximity or in
5 contact with the skin of the patient. More specifically, the present invention provides a flexible, high-intensity flexible phototherapy device that can be safely and comfortably worn.

Background of the Invention

10 The term "phototherapy" relates to the therapeutic use of light, and as used herein, the term "illuminator" refers to a device that is intended to be used externally to administer light to the skin for therapeutic purposes. Some phototherapy devices, in contrast, are provided on
15 probes and are designed to be used internally.

External phototherapy has been shown effective in treating various medical conditions. For example, studies have shown that certain light spectra are effective in treating bulimia nervosa, herpes, psoriasis, seasonal
20 affective disorder, sleep disorders, acne, and other conditions. One of the conditions most widely treated with phototherapy is hyperbilirubinemia in newborn infants, typified by an elevated level of a toxic molecule known as bilirubin in the infant's blood. During a natural process
25 where the body scavenges iron from a substance known as "heme," bilirubin is produced. Normally, bilirubin is conjugated within the liver and excreted. A fetus cannot conjugate bilirubin, however, so it is cleared via the placenta. During the initial neonatal period, the infant's
30 liver may be too immature to conjugate bilirubin. If the condition remains untreated, the serum bilirubin levels may

increase to the clinical condition of jaundice, since there is no effective excretory pathway. High levels of bilirubin in the neonate may cause irreversible brain damage and even death.

5 About 60 percent of newborns become clinically jaundiced at some time during the first week of life. Consequently, hyperbilirubinemia is one of leading causes of hospital readmissions of newborns. Phototherapy is the treatment of choice for neonatal unconjugated
10 hyperbilirubinemia, and has been used worldwide for decades with no known significant side effects. Phototherapy treats hyperbilirubinemia by changing bilirubin from its non-water-soluble form to water-soluble byproducts which can be bound to albumin, transported to the liver, and
15 excreted.

As a yellowish pigment, bilirubin absorbs visible light in the blue, violet, and green spectra, and most readily absorbs wavelengths in the range of 400-500 nm, with a maximum absorption peak in the 450-460 nm range,
20 i.e., blue light. Green light is also effective in phototherapy because light of longer wavelengths penetrates the skin more deeply. There is a dose-response relationship in the efficacy of phototherapy. That is, there is an increased response for higher doses of
25 therapeutic light, as shown by a decrease in bilirubin levels.

Illuminators for phototherapy which are known in the art fall into two general categories: banks of light and fiber-optic illuminators. The earliest phototherapy
30 illuminators included banks of light placed over an incubator, above an open bassinet, under a hood, or under a transparent support. Either fluorescent tubes or metal halide lamps typically serve as the light sources, although arrays of LEDs are also known in the art. These light
35 sources are spaced from the infant and illuminate the whole

body of the infant.

5 Illuminators using banks of light suffer from a number of drawbacks. The infant must wear sometimes uncomfortable eye protection during this treatment, either by using an appropriate shield or goggles, or even by taping the eyes shut, because the intense light can cause permanent eye damage. The relatively large size of the equipment takes up valuable free space in a typically cramped neonatal hospital ward. The banks of lights generate undesirable heat, and interfere with personnel attending to the patient. The heat generated is of vital concern in infant phototherapy. Newborn infants are extremely sensitive to heat, and it has been found that the heart rate of preterm infants increases significantly when the environmental temperature is raised as little as five degrees Celsius above normothermia. Hyperthermia has been associated with heart irregularities, heatstroke, and sudden infant death syndrome. Consequently, the infant's temperature must be frequently monitored when the infant is under a bank of phototherapy lights. Moreover, the relatively bulky equipment is not well-suited for home use, and thus the newborn infant must remain longer in the hospital.

Primarily in response to the desire of parents to bring their newborn infant home sooner, portable fiber-optic pads or wraps have been developed. These fiber-optic illuminators transmit light from a remote source through a fiber-optic cable to a flexible pad having a weave of optical fibers which can be worn next to the patient's skin. Because fiber-optic illuminators are placed around or under only a portion of the infant, its eyes are not exposed to intense light and eye protection is not necessary. Because the light source is remote from the flexible pad next to the patient, a filter can be used to attenuate any appreciable heating. Most importantly, since infant can be held and attended to while undergoing

phototherapy treatment, fiber-optic illuminators promote better infant-parent bonding during the first few weeks of life. Commercial fiber-optic phototherapy illuminators include Ohmeda's BiliBlanket and Respironics' Wallaby II, which have tungsten halogen lamps and quartz halogen lamps, respectively, as their light sources.

Figure 1 illustrates a fiber-optic pad type of illuminator of the prior art. The illuminator includes a woven fiber-optic pad 10 connected by a cable 12 to a housing 14 for a source of light. The connector 16 is affixed to an end of the cable 12 and is inserted into the housing 14 to receive the light energy. The housing 14 includes the front face 24 on which may be mounted a power switch 20, a control indicator 22, and indicator lights 26 and 28. The pad 10 comprises a plurality of optical fibers woven so as to emit light energy from one side of the pad.

Despite several advantages over radiant-type illuminators, fiber-optic illuminators are not ideal for several reasons. Significantly, fiber-optic illuminators typically deliver a lower overall amount of light than overhead banks of light, because the light is transmitted from a remote source to a relatively small fiber-optic pad. Moreover, to deliver even this limited amount of light, fiber-optic illuminators require a high-intensity light source such as halogen lamp, and an expensive optical filter to eliminate unwanted heat and ultraviolet light. Fiber-optic pads typically rely upon the geometry of the various emitting layers of fiber to control the level of light emittance. Since the patient is in direct contact with the fiber-optic pad, there is some pressure applied which may change the geometry, and thus change the level of light. Finally, the light intensity may be more concentrated near the light source than at the other end of the pad.

Recently, researchers at Stanford University have

studied the efficacy of high-intensity light-emitting diodes (LEDs) for phototherapy of hyperbilirubinemic neonates. The in vitro photodegradation of bilirubin in human serum albumin from both LEDs and conventional light sources was measured, with the conclusion that LEDs are more effective. The use of LEDs for use in home phototherapy devices was mentioned. However, no specific device structure was disclosed, nor was any consideration given for the safety and comfort of the patient, for example newborn infants, undergoing phototherapy..

In sum, fiber-optic illuminators are less effective than traditional overhead phototherapy illuminators, and both have significant disadvantages. In addition, there remains a number of hurdles, for example, relating to patient safety and comfort as well as therapeutic effectiveness, to the use of LEDs in home phototherapy devices. There thus remains a need for a phototherapy illuminator which delivers a higher intensity of therapeutic light than current fiber-optic illuminators, while retaining the advantages of a flexible light-emitting pad and being safe and comfortable in use.

Summary of the Invention

In accordance with one aspect of the present invention, an illuminator for delivering light energy to the skin for phototherapy is disclosed. The illuminator comprises a thin, lightweight flexible substrate having a plurality of conductive traces affixed thereto adapted to connect to electrical power source. At least one discrete light generating source, preferably at least two discrete light-generating sources, are disposed on the substrate and are coupled to the conductive traces. Finally, a covering at least partly surrounds the substrate and has an exterior surface that is spaced apart from the light-generating

sources, the exterior surface being adapted to contact the skin of patient. Desirably, the illuminator is sufficiently lightweight and flexible to be worn against the skin of a newborn infant without injury. The
5 illuminator preferably includes a light diffuser to render the light energy from the discrete light-generating sources more uniform. Additionally, the cooling means is desirably provided to maintain the exterior surface below a predetermined temperature.

10 In another embodiment, the present invention provides an illuminator for delivering light energy to the skin for phototherapy, comprising a thin, lightweight substrate, a plurality of conductive traces affixed to the substrate and adapted to connect to an electrical power source, at least
15 one light-generating source disposed on the substrate and coupled to the conductive traces, and an interface at least partly covering or adjacent the light-generating source on the substrate.

As used herein, the term "interface" refers to a
20 region of the present illuminator located at least partially around and/or at least partially adjacent the light generating source or sources of the illuminator. The interface can include a hollow or open space or passage.

The interface advantageously provides or is adapted to
25 carry an effective heat transfer means or medium to dissipate heat generated by the light-generating source or sources so that the illuminator can safely contact the skin of the patient, for example, a neonate. In one useful embodiment, the illuminator includes a covering and the
30 interface provides or is adapted to carry a cooling means or medium between the covering and the substrate. For example, the interface may define spaces between the covering and a substrate for passive or active heat transfer. The illuminator may be provided in a flexible
35 mat connected to one or more conduits carrying electrical

wires and the cooling fluid medium.

In a still further embodiment, an illuminator of the present invention for delivering light energy to the skin for phototherapy comprises a thin, lightweight substrate and a plurality of conductive traces affixed to the substrate adapted to connect to electrical power source. At least one discrete light source, preferably at least two discrete light sources, disposed on the substrate are coupled to the conductive traces. An interface at least partly covers the light-generating sources on the substrate, and is effective to diffuse the light emitted from the discrete light source or sources. The illuminator is adapted to contact the skin of the patient. The interface may include any suitable light diffuser or diffusers. For example, light scattering elements, such as glass bubbles or hollow glass beads, and the like may be employed. Other light scattering elements include, but are not limited to, grains or particles of titanium oxide, titanium dioxide, zirconium oxide, zinc oxide, quartz, aluminum oxide, diamond dust, calcium carbonate, calcium fluoride, flint glass, barium fluoride, other glasses, material which has a refractive index different, e.g., by at least about 5%, from the refractive index of the matrix in which the light scattering elements are placed, and the like and mixtures thereof. The interface may include indentations, texturing and the like surface features to diffuse the light. A reflector or reflectors may be employed to diffuse light. Also, a lambertian (random) reflecting surface or surfaces, for example, a white surface or surfaces, may be employed to diffuse light. Of course, combinations of two or more light diffusers can be employed.

The interface may comprise a silicone matrix with glass beads or bubbles, for example, hollow glass beads, dispersed therethrough, or a blend, mixture or combination

of materials having different refractive indexes. Alternately, or in addition, the interface may have an exterior surface adapted to contact the skin of a patient, which surface is irregular, for example, having a matte
5 finish, to defuse the light emitted from the discrete light source or sources.

In one preferred embodiment of the invention, light scattering elements, such as glass bubbles and the like, are positioned in proximity to the surface of the
10 illuminator to be in contact with the patient, that is the contact surface. The light sources or sources are located further back or away from the contact surface and a flexible lambertian reflecting surface is located still further away from the contact surface. This arrangement
15 reduces the loss of light and enhances light diffusion and utilization. The illuminator is placed against the skin of the patient, leaving substantially no room for the light to escape. The reflecting surface is effective to return light scattered by the patient's tissue and/or the
20 diffusing elements back to the patient until it is absorbed, and does so at a close distance, maintaining light intensity. Concentrated light from the light source is spread over the surface of the reflector, further enhancing diffusion. This arrangement also allows the use
25 of additional diffusing material while maintaining a substantially constant level of light output.

Preferably, the average irradiance at the light emitting or contact surface of the present illuminators is more than about 50 micro watts per square centimeter.

30 In a further aspect of present invention, a wearable phototherapeutic illuminator for delivering light energy to the skin comprises a flexible substrate and a least one light-generating source disposed on the substrate. A flexible, polymer layer covers the light-generating source,
35 the layer permitting light energy to penetrate therethrough

and being adapted to substantially conform, or structured to be capable of substantially conforming, to a portion of the skin of the patient. The layer is desirably a material chosen from the group consisting of silicone, urethane, and polyurethane. There may be a plurality of the light-generating sources, and a plurality of glass bubbles, or a blend of materials having different refractive indexes, may be dispersed throughout the layer to defuse the light emitted from the light-generating sources.

Each of the features disclosed herein is included within the scope of the present invention. In addition, all combinations of two or more of the presently disclosed features which are not mutually inconsistent or incompatible are also included within the scope of the present invention.

These and other aspects and advantages of the present invention are apparent in the following detailed description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

Brief Description of the Drawings

Figure 1 is a perspective view of a prior art fiber-optic illuminator;

Figure 2 is a perspective view of a flexible pad-type illuminator of the present invention;

Figure 3 is a schematic view of a phototherapy system utilizing a flexible pad-type illuminator of the present invention;

Figure 3A is a schematic illustration of the control housing of the phototherapy system shown in Figure 3;

Figure 4 is a perspective view of alternative mat-type illuminator of the present invention;

Figure 5 is a perspective view of a flexible pad-type

illuminator of the present invention wrapped around an adult limb;

Figure 5A is an illustration of an illuminator of the present invention in the form of a mask to be worn on the face of an adult or adolescent human.

Figure 6 is a plan view of a pad-type illuminator of the present invention showing sequential layers cutaway;

Figure 7 is a sectional view through a portion of the illuminator of Figure 6;

Figure 8 is a sectional view through a portion of an alternative illuminator similar to that shown in Figure 6;

Figure 9 is a plan view of a substrate and electronic connections for a plurality of light-generating sources used in an exemplary illuminator of the present invention;

Figure 10 is a partial cutaway view of internal cooling channels formed in an exemplary illuminator of the present invention;

Figures 11A-11D are cross-sectional views showing various constructions of the illuminator of the present invention;

Figures 12A-12F are cross-sectional views showing further constructions of the illuminator of the present invention;

Figures 13A-13D are cross-sectional views showing still further constructions of the illuminator of the present invention;

Figures 14A-14C are plan views of illuminators of the present invention having passive cooling channels therein;

Figures 15A-15C are perspective views of illuminators of the present invention having external cooling fins formed thereon; and

Figure 16 is a perspective view of an alternative illuminator having internal spacer pins.

Figure 17 is a perspective illustration showing a still further construction of an illuminator in accordance

with the present invention.

Figures 17A-D are schematic illustrations of various patterns useful in the construction illustrated in Figure 17.

5 **Description of the Preferred Embodiments**

10 The present invention provides a flexible illuminator having a variety of applications, such as for the treatment of hyperbilirubinemia in neonates, and psoriasis, seasonal affective disorder, sleep disorders, herpes, acne, and other medical conditions. The invention is an advance over current fiber-optic type illuminators because of the increased intensity of the light sources. Various configurations are described herein, none of which should be construed as particularly preferred in general.

15 Instead, each configuration may be preferred in certain applications over others.

Illuminator System

20 Figure 2 illustrates an illuminator 30 of the present invention comprising an elongate flexible body 32 having a front or contact surface 34 and a back surface facing the opposite direction and not seen in Figure 2. In the embodiment illustrated, the illuminator 30 has a rounded rectangular configuration with a length L, a width W, and a thickness t, with the length L being substantially greater than the width W, both of which are substantially greater than the thickness t. The proportion of these dimensions is preferred to enable the illuminator 30 to be wrapped around a small infant, or around the limb of an adult, as seen in Figures 3 and 5, although those of skill

25 in the art will understand that other configurations are possible.

30 As will be described in more detail below, the illuminator 30 contains a plurality of electric light-

generating sources, and thus a power cable 36 attaches to a first narrow end 38 of the body 32. The body 32 is thicker in a region 40 adjacent the first end 38 to provide strain relief at the interface between the body and cable 36. In one particular preferred embodiment, the body 32 is molded around the light-generating sources and power cable 36, with the thickened region 40 being formed accordingly. As will also be described below, the illuminator 30 may include means for transferring heat away from the front surface 34, which may involve flow of a cooling medium to interior channels formed in the body 32. In that case, the jacket around the power cable 36 may also provide a conduit for delivery of the cooling medium to and from the illuminator 30.

Illuminator Configurations

Figures 3, 3A, 4, 5 and 5A illustrate several potential configurations of the illuminator of the present invention. In Figure 3, an illuminator 44 similar to that shown in Figure 2 is wrapped completely around the abdomen of an infant patient. The illuminator 44 may be secured in this position using straps, Velcro, adhesive tape adhered to a disposable cover, or other such attachment means. A cable 46 supplies electricity and cooling medium from a control housing 48 to the illuminator 44, as mentioned above. Figure 3 schematically illustrates a control assembly 49 (of conventional design) providing electricity to illuminator 44 through power conduit 51. Control assembly 49 also controls the operation of an active cooling system 50 including a source of cooling medium 52 and a pump 54. Source 52 may include cooling coils or other suitable assembly for maintaining the temperature of the cooling medium or coolant at a desired level. A pair of conduits 56 and 57 deliver the cooling medium to the illuminator 44 and return medium to be cooled to the system

50.

Figure 4 illustrates a larger, mat-type illuminator 60 upon which an infant may be placed. A single cable 62 supplies power (and possibly cooling medium) to the illuminator 60.

Figure 5 illustrates a pad-type illuminator 64, much like the illuminator 30 illustrated in Figure 2, that is wrapped around the patient's limb and fastened with Velcro hook/loop fastener patches 66. Again, a single conduit 68 delivers power and potentially cooling medium to the illuminator 64.

Figure 5A illustrates a further specialized form of an illuminator in accordance with the present invention. This illuminator 61 is in the form of a mask to be placed on the face of an adult or adolescent human. An elastic band 63 is attached to mask 61 and is placed around the patient's head to secure the mask in a desired position on the face. Eye holes 65, nose hole 67 and mouth hole 69 are provided so that the eyes can be protected from the light and normal breathing/talking can occur while the patient is being treated, for example, for acne. A single conduit 59 delivers electrical power and possibly cooling medium to the mask 61.

Illuminators in accordance with the present invention can be formed into any suitable configuration to treat various medical conditions, as described herein, while also protecting the patient from unwanted, and possibly harmful exposure to light and/or heat. For example, the present illuminators can be configured to be placed on the face, like a wash cloth, for the treatment of seasonal affective disorder, as well as acne and other skin conditions; or can be configured similarly to a sanitary napkin, tampon or condom for the treatment of herpes.

In short, the forms of the present illuminators illustrated are not intended, and should not be taken, to

be limiting.

Exemplary Illuminator Construction

Figures 6-7 illustrate the internal construction of an illuminator similar to that shown in Figure 2. The plan view of Figure 6 shows one end of the body 70 of the illuminator with sequential layers stripped away from right to left. These layers can be seen in cross-section in Figure 7. The front or contact surface 71 of the body 70 faces out of the page in Figure 6. Therefore, a front covering 72 is seen on the right side of Figure 6, and is cut away at line 74 to reveal an array of light-generating sources 76. A plurality of glass bubbles 73 (right side of Figure 7) are randomly located in front covering 72 to scatter or diffuse light, as discussed hereinafter. In this embodiment, a plurality of transversely extending spacers 78 surround the sides of each of the light-generating sources 76, and are spaced from one another to provide cooling channels 80 therebetween. The spacers 78 may or may not at least partially encapsulate the sources 76. Such encapsulation is preferred to enhance dissipation of heat and light diffusion, and to protect the light sources from physical damage and/or detachment. As is apparent from Figure 6, the cooling channels 80 extend in a serpentine fashion along the length of the body 70. The layer of spacers 78 is cut away at line 82 in Figure 6 to reveal a substrate 84 on which the light-generating sources 76 are mounted. In addition, an array of conductive traces 86 is provided on the substrate 84 to power the light-generating sources 76. Continuing to the left in Figure 6, the substrate layer is cut away at line 88 to reveal a layer of secondary spacer material 90 within which is formed a secondary cooling channel 92. Again, the cooling channel 92 extends in a serpentine fashion along the length of the body 70 and adjacent the substrate. Finally, the

secondary spacer material 90 is cut away at line 94 to reveal a back cover 96.

Alternative Illuminator Construction

Figure 8 illustrates, in cross-section, an illuminator 100 having a substrate 102 with a plurality of light-generating sources 104 mounted thereon. An array of spacers 106 between cooling channels 108, as in Figure 7, is provided. In addition, an insulating layer 110 and outer covering 112 are included in the combination of components making up the interface. Also included are a plurality of glass bubbles 111 located in a relatively well defined layer in outer covering 112 to scatter or diffuse light, as discussed hereinafter. As with Figure 7, the backing comprises the secondary spacer 114 and secondary cooling channels 116 encompassed by the back cover 118. The addition of an insulating layer 110 further helps to prevent heat transfer from the light generating sources 104 to the contact surface of the illuminator.

Internal Illuminator Systems

Figure 9 is a cutaway view of one end of an illuminator 120 of the present invention showing the interface between a power cable 122 and an array of conductive tracings 124 providing a conductive path to a plurality of light-generating sources 126. A wire 128 electrically connects to a pole 130 that is in electrical communication with the negative terminal of each of the light-generating sources 126. Likewise, a wire 132 electrically connects to a pole 134 that is in electrical communication with the positive terminal of each of the light-generating sources 126. The wires may be electrically connected to the tracings by lap soldering to the pole or bus bar or through use of DIMM or MOLEX-type multiconductor connectors. In this embodiment, the light-

generating sources are provided in seventeen rows across the width of the illuminator 120, and are staggered from column to column. That is, a first column 136 of nine light-generating sources is followed by a second column 138 of eight light-generating sources in different rows of conductive tracings 124. This pattern repeats itself along the length of the illuminator 120.

Figure 10 illustrates the relative positions of the light-generating sources 126, a first cooling channel 140, and secondary cooling channel 142 provided below the substrate. Arrow 144 indicates an inflow of cooling medium to the first cooling channel 140, which medium flows between columns of light-generating sources 126. The horizontal cutaway line 146 reveals the secondary cooling channel 142 below the substrate. Although not shown, the first cooling channel 140 is in fluid communication with the secondary cooling channel 142 at the opposite end of the illuminator. That is, the cooling medium flows along the length of the illuminator 120 (from right to left), and then passes across the plane of the substrate (i.e., into the page) through an opening into the secondary cooling channel 142. The cooling medium then flows (from left to right) along the length of the secondary cooling channel 142 until it exits the illuminator, as indicated by arrow 148.

Figure 10 thus illustrates active cooling of the illuminator 120, wherein cooling medium is propelled through internal channels. The cooling medium in this regard may be in liquid or gaseous form, with air being preferred to avoid increasing the weight of the illuminator 120 in use. Of course, other arrangements of cooling means are possible, as will be described in more detail below.

Functional Considerations

Now with reference more particularly to the cross-

section of Figure 7, the illuminator can be viewed more generally as including the light-generating sources 76 mounted on the substrate 84, and an interface provided between the substrate 84 and a front or contact surface 98.

5 In the illustrated embodiment, contact surface 98 comprises the outer surface of the covering 72, while the interface comprises a combination of the covering, the spacers 78, and the cooling channels 80. In addition, the illuminator preferably includes a backing, which in this embodiment
10 comprises the secondary spacers 90, secondary cooling channels 92, and back cover 96. The invention may be best described in terms of the preferred functional characteristics of the interface and the backing, as follows.

15 The interface preferably performs two main functions: heat insulation and light diffusion. That is, the separate light-generating sources 76 generate some heat in operation which must be intercepted and carried away or attenuated before it reaches the contact surface 98. Therefore, the
20 interface preferably provides a thermal barrier to heat conduction, and may also include a system of passive or active cooling, facilitated by the cooling channels 80. In addition, the light-generating sources 76, being discrete and spaced apart, create a plurality of points of intense
25 light, rather than an even distribution. Therefore, the interface preferably diffuses the discrete points of light to provide a more uniform emittance. In addition, the interface performs other functions. For example, the interface protects the light sources and circuitry from
30 damage and/or detachment, reduces or even eliminates the risk of exposing the patient to electrical current, and provides additional padding to enhance the comfort of the patient.

The backing preferably performs two main functions as
35 well: heat conduction and light reflection. That is, the

backing preferably provides an effective heat sink for the heat generated by the light-generating sources 76, which works in conjunction with the heat barrier provided by the interface to cause heat to travel away from the contact surface 98. In this manner, the secondary spacer 90 is preferably made out of a highly conductive material that is in intimate contact with the backside of the substrate 84. The backing also protects the circuitry and light sources, protects the patient from electrical current and provides added padding to enhance patient comfort.

As will be apparent from the variations in construction that follow, numerous combinations of the interface and backing are possible. Because of the numerous configurations that the illuminator can take, as seen for example in Figures 3-5, there is no single optimum construction, but rather the functional characteristics described above are desirably provided in the most cost-effective manner for the particular application. Thus, for example, if the illuminator is to be used as a mat, as seen in Figure 4, additional padding between the substrate 84 and light-generating sources 76 may be required, which will increase the thickness of the interface and/or backing. Similarly, for an elongated pad-type illuminator, as seen in Figures 2-3 and 5, padding is not as important as the illuminator being flexible and lightweight. Additionally, the contact surface of the illuminator must be relatively soft and preferably hypoallergenic if it is to be used for treatment of hyperbilirubinemia in neonates.

The illuminator may be formed into a variety shapes, such as a pad or mat shown. Alternatively, the illuminator can be formed into a belt, a wrap, a cushion or pillow, a collar, a blanket, a strap, a vest, or any other desired shape. Advantageously, the particular shape and ultimate configuration on the patient does not affect the quality and intensity of the light delivered, as with prior fiber

optic devices.

Light Diffusion

At least a portion of the interface preferably causes the light emitted by the plurality of light-generating sources to be diffused or directed as desired. Such diffusion or direction is effective to provide a more uniform, constant and intense light pattern on the contact surface relative to a similar apparatus including a plurality of discrete light emitting sources without light diffusion. Therefore, the interface may be made of a single material or blend of materials having different refractive indices, such as silicone and glass bubbles or silicone and titania. Thus, in Figure 7, the front cover 72 comprises a matrix of silicone within which a plurality of glass bubbles is randomly impregnated. Figure 8 illustrates a cover 112 which comprises a matrix of silicone having a plurality of more evenly distributed glass bubbles 111. It should be noted that the size of the glass bubbles in the figures is exaggerated for illustration purposes. Alternatively, or in addition, the covering 72 or 112, or the insulating layer 110, may be provided with deformities or markings formed by mechanical, chemical, or other means to cause light emitted by the light-generating sources to diffuse. Such deformities or markings can be formed by molding, cutting, hot stamping, etching, painting, machining, coating, forming, milling, or printing. The deformities may vary in density, opacity, shape, color, index of refraction, size, depth and shade so as to produce a desired diffusion or light distribution. In one embodiment, such surface deformities are created by roughening the surface of the cover mold with glass beads or sand so as to give the surface a matte finish. The interface, such as the covering, may vary in color, index of refraction, or shape along the length of the

illuminator. A reflector or reflectors may be used to diffuse light. Lambertian reflectors also can be used. Prismatic films and diffusers, lenticular lenses, coatings, and other systems or materials may be used to cause light to be diffused as desired. Reflective paints or coatings, such as coatings of magnesium oxide, aluminum oxide, other white powders and the like and mixtures thereof, are useful for diffusion.

Figures 17, 17A, 17B, 17C and 17D illustrate the use of such paints or coatings. An LED 504 is shown positioned relative to a light reflecting surface 506 of illuminator 510 in accordance with the present invention. Reflecting surface 506 can be a metallized surface or a surface with a matte finish or the like. Contact surface 512 is part of the interface of illuminator 510 and is spaced apart from LED 504. Arc 514 is a representation of the intense light pattern on contact surface 512 generated by LED 504 with no light diffusion. The light within arc 514 is very intense while the light from LED 514 outside the arc is substantially less intense and may not be therapeutically effective.

Figure 17A illustrates a pattern of white dots 520 that can be painted or coated on contact surface 512 within the arc 514 to diffuse the intense light. The diameter of the dots decreases from the center of the pattern outwardly. This pattern of dots 520 scatters and/or reflects some of the light back to the reflecting surface 506. The pattern of dots depends, for example, on the thickness of the layer on which the contact surface is located and its distance from LED 504, and the presence of any additional light diffusing material or materials in the interface. The pattern of dots 520 results in a substantially more diffuse, yet therapeutically effective light pattern on the contact surface 512.

Figures 17B, 17C and 17D illustrate alternate coating

patterns that can be used in place of dots 520. Thus, a pattern of rectangles 522, a pattern of outwardly radiating lines 524 or a series of circles 526 can be used in much the same way as dots 520 to provide for enhanced light diffusion.

The interface may also comprise filters to reflect or absorb certain wavelengths of light. In order to control the exposure of the patient to ultraviolet radiation, or to minimize the deteriorative effect of such radiation on the illuminator, a layer or coating of or containing an ultraviolet absorber may be used. For example, the insulating layer 110 shown in Figure 8 may instead represent an ultraviolet filter. Examples of ultraviolet absorbers include bezophrenones, benzotriazoles, and salicylates. In addition, the illuminator made further comprise additives, including infrared absorbers (e.g., metals), antioxidants, coloring agents, plasticisizers, stabilizers, and antistatic agents.

Flexible Substrate

The present invention utilizes any type of flexible circuitry substrate known in the arts. Typically, the term "flexible substrate" pertains to polymeric sheets which may be bent or rolled without breaking. In one embodiment, the substrate may be said the flexible if it can be rolled, without breaking, into a cylindrical tube having a diameter less than 30 cm, and more preferably less than 5 cm. Examples of such flexible substrates are flexible printed circuitry laminates, which are composites of methyl conductors and dielectric substrates bonded together by an adhesive system. Other flexible substrates may not use adhesives, such as copper foil which is electrolytically deposited or rolled-annealed.

The substrates should be flexible and cable of withstanding the heat generated during the manufacturing

process and by the light-generating sources. Consideration should also be given to the dimensional stability, chemical resistance, electrical properties, flame retardancy, and cost. Substrates can be either thermosetting or thermoplastic polymers, such as polyester and polyimide films.

If an adhesive is used to secure the conductive tracings to the substrate, consideration should be given to the thermal properties of the adhesive. Desirably, the adhesive is highly heat conductive to further facilitate conduction of the heat generated by the light-generating sources throughout the substrate and to adjacent heat sinks.

The flexible substrate may comprise a reflector on the side facing the contact surface for directing light from the light-generating sources toward the contact surface. The reflector may be a thin, flexible sheet adhered to the flexible substrate. Alternatively, the reflector may be comprised of reflective materials coated directly on the flexible substrate. The reflector is desirably perforated in the locations of the light-generating sources and may be coated to reflect an appropriate wavelength or range of wavelengths of light. The reflective materials may be metals such as aluminum, silver or gold (or alloys thereof), or dielectrics coated at thicknesses designed to reflect desired wavelengths, or reflective paint. In one embodiment, the reflector provides lambertian reflectance, for example, reflects light by using a paint or coating which is white or matches the color of the LEDs.

Conductive Tracings

The flexible substrate may be coated, cast, deposited, or otherwise adhered to the conductive tracings or vice versa. In a preferred embodiment, the conductive tracings are directly adjacent to and in contact with the flexible

substrate. Alternatively, one or more additional layers may be present between the conductive traces and flexible substrate, such as when adhesives are used. The conductive tracings may be a variety of materials, including rolled-annealed copper, electro-deposited copper, silver, gold, aluminum, iron, steel, solder, or any other metal or conductor. The conductive coating may be applied as, or processed into, tracings using any means for application or removal, including chemical, mechanical, and optical means, as well as the use of lasers. In a preferred embodiment, a plurality of pairs of parallel conductive traces are etched into the rolled-annealed copper coating of a flexible substrate, for example, using conventional photo-etching techniques.

Polymer thick films including one or more finely divided conductive materials like silver, nickel, or carbon in a polymer binder like polyester, epoxy, acrylic, or vinyl also may be used. Polymer thick film printed wiring is less expensive than copper conductors since it is generally formed in a single step using screen printing, without traditional plating, etching, stripping, and cleaning. Examples of polymer thick films which offer an alternative to other types of circuitry are available from Du Pont as the CB® series polymer thick film pastes.

An insulating film or coating may be applied over the conductor surface to protect the circuitry for moisture, contamination, and conductor damage, and to reduce stress on the conductors during flexing. These protective coatings may be overlays comprising an insulating film coated with an adhesive, a coating comprising liquid polymers applied to the circuit, leaving the pad areas exposed, and solder masks comprising film laminates into which conductor access holes have been formed. Adhesives such as epoxies and polyimide resins may be used for overlays and laminations.

Light-generating Sources

The light-generating sources are preferably a light-emitting diode (LED) chip or die of the surface mount variety. Alternatively, other types of LEDs, lasers, and laser diodes also may be suitable. The light-generating sources may be multicolored LEDs, or a combination of multiple colored LEDs, a combination of different LEDs, or arrangement of the same type of LEDs, depending on the desired color, distribution or pattern.

For the treatment of neonatal hyperbilirubinemia, the preferred color of LEDs is blue, although green LEDs also may be effective. The treatment of other conditions may require different colored LEDs. For example, herpes may be most effectively treated by red LEDs, seasonal affective disorder may be treated by white or yellow LEDs, and psoriasis may be treated by ultraviolet LEDs.

The illuminator of the present invention may include any suitable interconnection technology to provide an electrical circuit among the LEDs, the substrate, the power supply, and any control device. In this regard, flexible or traditional wiring, solder attachment, conductive pieces, and/or pressure connectors may be used. A preferred embodiment utilizes surface mount technology to adhere the light-generating sources to the flexible substrate. Such manufacturing technologies may comprise surface mount-on-flex (SMT), chip-on-flex (COF), flip chip-on-flex (FCOF), micro-surface mount technology (micro SMT), micro-ball grid array (micro BGA), controlled collapsed chip connection (C4), or any known method of manufacture or assembly.

Illuminator Control

The illuminator may comprise a controller capable of making the light-generating sources separately addressable so that they may be selectively illuminated in a particular

pattern to achieve a particular therapeutic result. In addition, the power level of one or all of the light-generating sources may be controlled to optimize the light intensity required, to mix colors where different LEDs are used, or to shut off light-generating sources in the case of overheating. In the latter instance, thermocouples may be provided in and around the light-generating sources, or on the contact surface, to monitor the temperature of the illuminator and provide feedback to the controller. Finally, the illuminator controller may contain a timer to assist in metering exposure of the patient according to doctor's instructions.

Cooling Means

The interface of the illuminator preferably occupies the space between the substrate and the external contact surface. The interface may contain fins, vanes, ridges, grooves, tubes, holes, channels, or other features to absorb or diffuse heat, to increase surface area for heat exchange, and/or to control or direct a flow of air, water or other fluids. Alternatively, the interface may be solid if heat is not a concern.

As will be apparent from the structural variations shown herein, the illuminator may include holes or spaces through the substrate, covering, or between the covering and substrate in locations which avoid interference with the conductive traces, light sources, and cooling fluids. The illuminator may utilize air or water, and an associated blower or pump to force the cooling fluid through spaces.

The interface may be made of silicone, urethane, polyurethane, or any flexible plastic or other translucent or transparent material, or colored material, and combinations thereof. As mentioned above, silicone with at least a portion having glass bubbles and/or titania impregnated therein is preferred.

Disposable Overwrap

The illuminator is desirably at least partly surrounded with a disposable overwrap as a contamination barrier between the illuminator and the skin of the patient. Such an overwrap may be thin polyethylene or cellophane, for example, and is preferably transparent so as not to interfere with the transmission of light to the patient. The overwrap is preferably loosely fitted over the illuminator in any form, and can be easily secured by tape or other means and removed for sanitary purposes and subsequent immediate re-use of the illuminator.

Alternative Illuminator Constructions

Figures 11-13 illustrate various cross-sections of illuminators in accordance with present invention showing the basic elements of a substrate, a light-generating source (in this case an LED), an interface between the substrate to a contact surface, and a backing. Consistent with the discussion above regarding the functional characteristics, these variations are helpful in illustrating the multiple permutations of materials and configurations that are possible in constructing an illuminator of the present invention.

Figures 11A-11D illustrates four cross-sections that all have a substrate 160, an LED 162, and an interface comprising a solid layer 164 of light-diffusing and heat-insulating material. The layer 164 has an exterior skin contact surface 166. One example of material for the layer 164 is silicone having glass bubbles distributed randomly throughout. Another example of material for the layer 164 is silicone having titania distributed throughout. Alternatively, or in addition, the layer 164 may be silicone having a matte finish on the skin contact surface 166. The skin contact surface may have a pattern, for example, a printed pattern, effective to scatter and

diffuse light.

In Figure 11A, the backing comprises a solid layer 168 of light-reflective, heat-conductive material. Figure 11B includes a backing comprising a solid layer 170 of light-diffusive, heat-conductive material. In Figure 11C, the backing comprises a back cover 172 spaced from a substrate 160 with a secondary spacer 174. The secondary spacer 174 includes gaps or channels 176 therein directly across the substrate 160 from each of the LEDs 162. In Figure 11D, the backing comprises a back cover 178 spaced from the substrate 160 with a secondary spacer 180. In this case, the secondary spacer 180 is provided directly underneath each of the LEDs 162, and preferably is made of a highly heat conductive material. Heat thus flows from the LED 162 through the substrate to the secondary spacer 180, which is cooled on either side by the gaps 182.

Figures 12A-12F all include the substrate 160, LED 162, and a front cover 190 whose exterior surface is intended to contact the skin of patient. In addition, each of the cross-sections in Figures 12A-12F include one or more gaps or channels for cooling.

In Figure 12A, the cover 190 is spaced from the substrate 160 with a spacer 192. The spacer 192 is formed directly over the LEDs 162 and defines gaps or channels 194. The backing comprises a solid layer 196 of light-reflective, heat-conductive material. In Figure 12B, the interface includes the aforementioned spacer 192 and channels 194, as in Figure 12A, but the backing comprises a back cover 198 spaced from the substrate 160 with a secondary spacer 200. In this embodiment, the secondary spacer 200 provides gaps or channels 202 directly underneath each of the LEDs 162.

Figure 12C shows a spacer 204 separating the cover 190 from the substrate 160, the spacer 204 providing gaps or channels 206 directly surrounding each of the LEDs 162. In

this embodiment, the interface is formed by the cover 190, spacer 204, and channels 206, and the cooling medium can flow directly over each of the LEDs 162. Again, the backing is provided by a solid light-reflective, heat-conductive layer 208. Figure 12D also illustrates the spacer 204 and channel 206, which together with the cover 190 comprise the interface, but the backing is provided by a spacer 210 and a back cover 212. The spacer 210 is directly underneath each of the LEDs 162 and forms gaps or channels 214 therearound.

Figures 12E and 12F are substantial mirror images of one another, each of which having cooling channels above and below the substrate 160. In Figure 12E, the interface comprises the cover 190, the spacer 220 directly surrounding each of the LEDs, and gaps or channels 222 defined by the spacer. The backing comprises a secondary spacer 224 directly underneath each of the LEDs 162, a back cover 226, and a plurality of gaps or channels 228 adjacent the secondary spacer. In Figure 12F, a spacer 230 separates the cover 190 from the substrate 160 and defines cooling gaps or channels 232 directly over each of the LEDs 162. The backing comprises a secondary spacer 234 separating a back cover 236 from substrate 160 and defining a plurality of cooling gaps or channels 238 directly underneath each of the LEDs 162.

Figures 13A-13D illustrates several illuminator cross sections with maximum spaces defined by vanes or walls between two covers. More specifically, each of the cross-sections in Figures 13A-13D includes the substrate 160, LED 162, a front cover 250, and a back cover 252.

Figure 13A includes a plurality of vanes or walls 254 spacing the front cover 250 from the substrate 160. Cooling gaps or channels 256 are defined by the walls 254 surrounding each of the LEDs 162. The backing comprises the back cover 252 spaced from the substrate 160 by

secondary walls 258. Again, and gaps or channels 260 are provided below the substrate for cooling purposes.

In the embodiment of Figure 13B, walls 262 extend between the front cover 250 and a coating layer 264 provided on top of the substrate 160. The coating layer extends into contact with each of the LEDs 162. As in Figure 13A, the walls 262 defined gaps or channels 266 surrounding each of the LEDs 162. The backing comprises secondary walls 268 extending between the back cover 252 and a coating 270, and gaps 272 provided directly underneath each of the LEDs 162.

Figure 13C is similar to that shown in Figure 13B and includes walls 274 extending between the front cover 250 and a layer 276 formed on the substrate 160. In this case, the layer 276 completely covers each of the LEDs 162. Cooling gaps or channels 278 are formed over each of the LEDs, and the covering protects each of the LEDs from the corrosive effect of a fluid cooling medium. Also, as in Figure 13B, the backing comprises secondary walls 280 spacing the back cover 252 from a layer 282 formed on the backside of the substrate 160. Again, cooling gaps 284 are provided below each of the LEDs.

Finally, Figure 13D includes a spacer 290 extending between the substrate 160 and a front cover 250. The spacer 290 covers the substrate 160, as at 292, but provides gaps or channels 294 for cooling. The backing comprises a secondary spacer 296 extending between the substrate 160 and the back cover 252, the spacer being generally solid but defining gaps or channels 298 directly below each of the LEDs 162.

Passive Cooling

Up to now, various configurations of illuminators of the present invention have been described having internal gaps or channels, the understanding being that cooling

medium actively flows therethrough. While active cooling is certainly one option, a less-expensive variant is passive cooling. Figures 14A-14C illustrate three embodiments of an illuminator pad having passive cooling channels therethrough.

Figure 14A illustrates an illuminator pad 300 having a plurality of columns of apertures 302 extending from the front side to the back side. Preferably, the columns of apertures 302 are formed in between each column of LEDs 304 for maximum heat dissipation. Of course, the apertures should avoid interference with any copper tracings or light sources. Figure 14B illustrates an illuminator 306 having a series of channels 308 extending along the width dimension. The channels 308 are desirably formed between each column 310 of the LEDs. Finally, Figure 14C illustrate an illuminator 312 having a series of longitudinal channels 314 formed therein. In all of the embodiments seen in Figures 14A-14C, the apertures or channels are open at both ends and serve to passively dissipate heat generated by the LEDs.

Another configuration facilitating passive cooling is the use of external fins, as seen in Figures 15A-15C. In particular, Figure 15A illustrates an illuminator 320 having a plurality of fins 322 extending in the width dimension. In Figure 15C, the external fins 324 extend in the longitudinal dimension. Finally, in Figure 15C, the fins extend both in the width and longitudinal dimensions in a waffle pattern. Also, as shown in Figure 15A, the fins 322 are located on both the top and bottom surfaces of the illuminator. Of course, the fins, if present at all, can be located on the top and/or bottom surfaces of the illuminator. These fins provide passive cooling for the illuminators, and may be provided on the front or rear surfaces, or both.

A still further variation of passive cooling is seen

in the illuminator 340 of Figure 16. For illustration purposes, the cover 342 of the illuminator 340 is shown in phantom to reveal a plurality of pins or spacers 344 extending between the substrate 346 and cover 342. The
5 side edges of the illuminator 340 remain open to permit passive cooling of the LEDs 348. Alternatively, the side edges may be closed and cooling medium flowed through conduit 350. In any event, the spacers 344 maintain a gap between the front cover 342 and the substrate 346 along the
10 length of the illuminator 340.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the
15 following claims.

WHAT IS CLAIMED IS:

1. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight flexible substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces; and

a covering at least partly surrounding the substrate and having an exterior surface that is spaced apart from the light-generating sources, the exterior surface being adapted to contact the skin of a patient.

2. The illuminator of claim 1, wherein the illuminator is sufficiently lightweight and flexible to be worn against the skin of a newborn infant without injury.

3. The illuminator of claim 1, which includes a plurality of discrete light-generating sources disposed on the substrate and coupled to the conductive traces.

4. The illuminator of claim 1, wherein the covering is configured to facilitate the effective dissipation of heat produced by the light-generating sources away from the skin of the patient.

5. The illuminator of claim 4, wherein the covering includes fins positioned to provide increased dissipation of heat produced by the light-generating sources away from the skin of the patient relative to a substantially identical covering without the fins.

6. The illuminator of claim 4, wherein the covering is spaced from the substrate and further including cavities between the covering and the substrate.

7. The illuminator of claim 1, wherein the covering at least partly defines an internal structure adapted to facilitate at least one of a) dissipation of heat produced by the light-generating sources away from the skin of the patient, and b) diffusion of light generally toward the skin of the patient.

8. The illuminator of claim 1, further including a reflector for reflecting light from the light-generating sources away from the substrate toward the patient.

9. The illuminator of claim 8, wherein the light-generating sources comprise surface mount LEDs, and the reflector comprises a thin, flexible sheet perforated with holes through which the LEDs project.

10. The illuminator of claim 1, further including cooling means for effectively dissipating heat generated by the light-generating sources so that the illuminator can safely and comfortably contact the skin of a patient.

11. The illuminator of claim 1, further including a disposable overwrap sized to at least partly surround the illuminator and provide a contamination barrier between the illuminator and the skin of the patient.

12. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the

substrate and being adapted to connect to an electrical power source;

at least one light-generating source disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating source on the substrate, the interface providing an effective heat transfer means to dissipate heat generated by the light-generating source so that the illuminator can safely contact the skin of a patient.

13. The illuminator of claim 12, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

14. The illuminator of claim 12, wherein the illuminator is flexible and adapted to conform to the skin of the patient.

15. The illuminator of claim 12, wherein the interface defines spaces between the covering and the substrate.

16. The illuminator of claim 15, wherein the spaces comprise channels for convective heat transfer.

17. The illuminator of claim 15, wherein there are a plurality of the light-generating sources, and the spaces are directly adjacent the light-generating sources.

18. The illuminator of claim 15, wherein the spaces are in communication with apertures provided through the substrate.

19. The illuminator of claim 12, wherein the interface comprises a insulating layer.

20. The illuminator of claim 12, further including means for passively cooling the light-generating source.

21. The illuminator of claim 12, further including means for active cooling of the light-generating source.

22. The illuminator of claim 12, wherein the illuminator defines a skin-contacting surface, the light-generating source has an intensity in excess of 50 microwatts, and the interface limits the maximum temperature of the skin-contacting surface to about 110°F.

23. The illuminator of claim 12, wherein the interface comprises a flexible, polymeric layer permitting light energy to penetrate therethrough and conforming to the skin of a patient.

24. An illuminator for delivering light energy to the skin for phototherapy, the illuminator comprising:

a thin, lightweight substrate;

a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

at least two discrete light sources disposed on the substrate and coupled to the conductive traces; and

an interface at least partly covering the light-generating sources on the substrate, the interface diffusing the light emitted from the discrete light sources, the illuminator being adapted to contact the skin of a patient.

25. The illuminator of claim 24, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

26. The illuminator of claim 24, wherein the interface comprises at least one material effective to diffuse light energy from the light source.

27. The illuminator of claim 24, wherein the interface comprises a blend of materials having different refractive indices.

28. The illuminator of claim 24, wherein the interface has an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the discrete light sources.

29. The illuminator of claim 24, wherein the light sources are LEDs.

30. The illuminator of claim 24, further including a reflective backing in intimate contact with the substrate and comprising a heat conducting material.

31. The illuminator of claim 24, wherein the substrate comprises a print circuit board.

32. The illuminator of claim 44, further including a reflector for reflecting light from the light sources away from the substrate.

33. A wearable phototherapeutic illuminator for delivering light energy to the skin of a patient, comprising:

a flexible substrate;

at least one light-generating source disposed on the substrate; and

a flexible, polymeric layer covering the light-generating source, the layer permitting light energy to penetrate therethrough and adapted to substantially conform

to the skin of a patient.

34. The illuminator of claim 33, wherein the illuminator is sufficiently lightweight to be worn against the skin of a newborn infant without injury.

35. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer comprising a transparent matrix with glass bubbles dispersed therethrough to diffuse the light emitted from the light-generating sources.

36. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer comprising a blend of materials having different refractive indices to diffuse the light emitted from the light-generating sources.

37. The illuminator of claim 33, wherein there are a plurality of the light-generating sources, the layer having an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the light-generating sources.

AMENDED CLAIMS

[received by the International Bureau on 26 December 2000 (26.12.00);
original claims 1 – 37 replaced by amended claims 1 – 36 (6 pages)]

WHAT IS CLAIMED IS:

1. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

5 a thin, lightweight flexible substrate;
a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

10 at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces;

a reflector located on the substrate for reflecting light from the at least one light-generating source toward the patient; and

15 a covering at least partly surrounding the substrate and having an exterior surface that is spaced apart from the light-generating source, the exterior surface being adapted to contact the skin of a patient.

20 2. The illuminator of claim 1, wherein the illuminator is structured to be placed in contact with the skin of a newborn infant and used without injury.

25 3. The illuminator of claim 1, which includes a plurality of discrete light-generating sources disposed on the substrate and coupled to the conductive traces.

30 4. The illuminator of claim 1, wherein the illuminator is configured to facilitate the transfer of heat produced by the at least one light-generating source away from the skin of the patient sufficient to prevent such heat from adversely affecting the patient.

5. The illuminator of claim 4, wherein the illuminator includes at least one fin positioned to provide increased transfer of heat produced by the

light-generating sources away from the skin of the patient relative to a substantially identical illuminator without the fin.

5 6. The illuminator of claim 4, wherein the covering is spaced apart from the substrate and further comprising at least one cavity between the covering and the substrate.

10 7. The illuminator of claim 1, wherein the covering at least partly defines an internal structure adapted to facilitate at least one of a) dissipation of heat produced by the light-generating sources away from the skin of the patient, and b) diffusion of light generally toward the skin of the patient.

15 8. The illuminator of claim 7, wherein the internal structure is adapted to both a) dissipate heat produced by the light-generating sources away from the skin of the patient, and b) diffuse light generally toward the skin of the patient.

20 9. The illuminator of claim 1, wherein the light-generating source comprises an LED, and the reflector comprises a thin, flexible sheet perforated with holes through which the LED projects.

25 10. The illuminator of claim 1, further including cooling means for transferring heat generated by the at least one light-generating source so that the illuminator can safely and comfortably contact the skin of a patient.

30 11. The illuminator of claim 1, wherein the exterior surface is defined by a disposable overwrap sized to at least partly cover the illuminator and provide a contamination barrier between the illuminator

and the skin of the patient.

12. An illuminator for delivering light energy to the skin of a patient for phototherapy, the illuminator comprising:

- 5 a thin, lightweight substrate;
- a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;
- at least one light-generating source disposed
- 10 on the substrate and coupled to the conductive traces; and
- an interface at least partly covering the light-generating source on the substrate, the interface providing heat transfer means for
- 15 passively or actively cooling the light-generating source and transferring heat generated by the light-generating source so that the illuminator can safely contact the skin of a patient.

13. The illuminator of claim 12, wherein the

20 illuminator is flexible and adapted to conform to the skin of the patient.

14. The illuminator of claim 12, wherein the interface defines spaces between the covering and the substrate.

25 15. The illuminator of claim 14, wherein the spaces comprise channels for convective heat transfer.

16. The illuminator of claim 15, wherein the heat transfer means actively cools the at least one light-generating source by convection using the channels.

30 17. The illuminator of claim 14, wherein there are a plurality of the light-generating sources, and the

spaces are adjacent to the light-generating sources.

18. The illuminator of claim 14, wherein the spaces are in communication with apertures provided through the external surface of the illuminator.

5 19. The illuminator of claim 12, wherein the interface comprises a thermal insulating layer.

20. The illuminator of claim 12, further including diffusing means for diffusing light emitted from the at least one light-generating source.

10 22. The illuminator of claim 12, wherein the interface comprises a flexible, polymeric layer permitting light energy to penetrate therethrough and conforming to the skin of a patient.

15 23. An illuminator for delivering light energy to the skin for phototherapy, the illuminator comprising:

 a thin, lightweight substrate;

 a plurality of conductive traces affixed to the substrate and being adapted to connect to an electrical power source;

20 at least one discrete light-generating source disposed on the substrate and coupled to the conductive traces; and

 an interface at least partly covering the light-generating source on the substrate, the
25 interface comprises a combination of at least two materials having different refractive indices so as to diffuse the light emitted from the discrete light-generating source, the illuminator being adapted to contact the skin of a patient.

30

24. The illuminator of claim 23, wherein the interface has an exterior surface adapted to contact the

skin of a patient, the exterior surface having surface deformities to diffuse the light emitted from the at least one discrete light-generating source.

5 25. The illuminator of claim 23, wherein the interface further provides heat transfer means for passively or actively cooling the light-generating source and transferring heat generated by the light-generating source so that the illuminator can safely
10 contact the skin of a patient.

 26. The illuminator of claim 23, further including a reflector for reflecting light from the at least one discrete light-generating source toward the patient.

 27. The illuminator of claim 26, wherein the
15 reflector is a diffusive reflector.

 28. The illuminator of claim 27 wherein the diffusive reflector has a Lambertian (random) reflecting surface.

 29. The illuminator of claim 23, wherein the
20 interface has an exterior surface adapted to contact the skin of a patient, the exterior surface being irregular to diffuse the light emitted from the discrete light sources.

 30. The illuminator of claim 23, wherein the at
25 least one discrete light-generating source is an LED.

 31. The illuminator of claim 23, further including a reflective backing in intimate contact with the substrate and comprising a heat conducting material.

30 32. The illuminator of claim 23, wherein the substrate comprises a print circuit board.

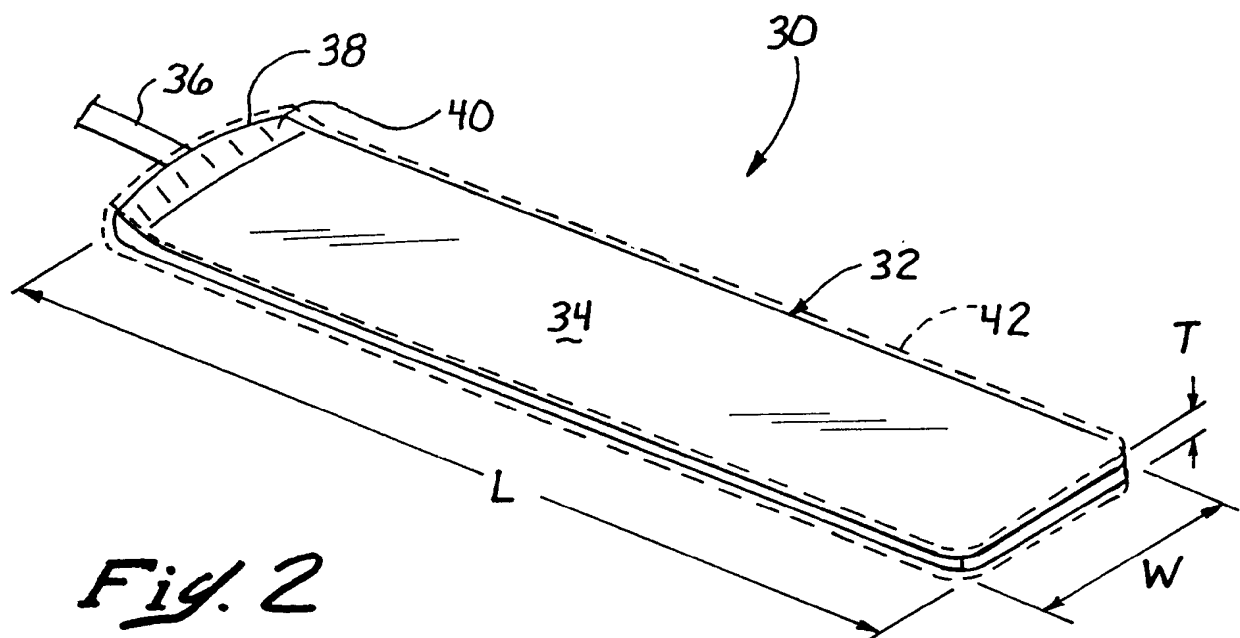
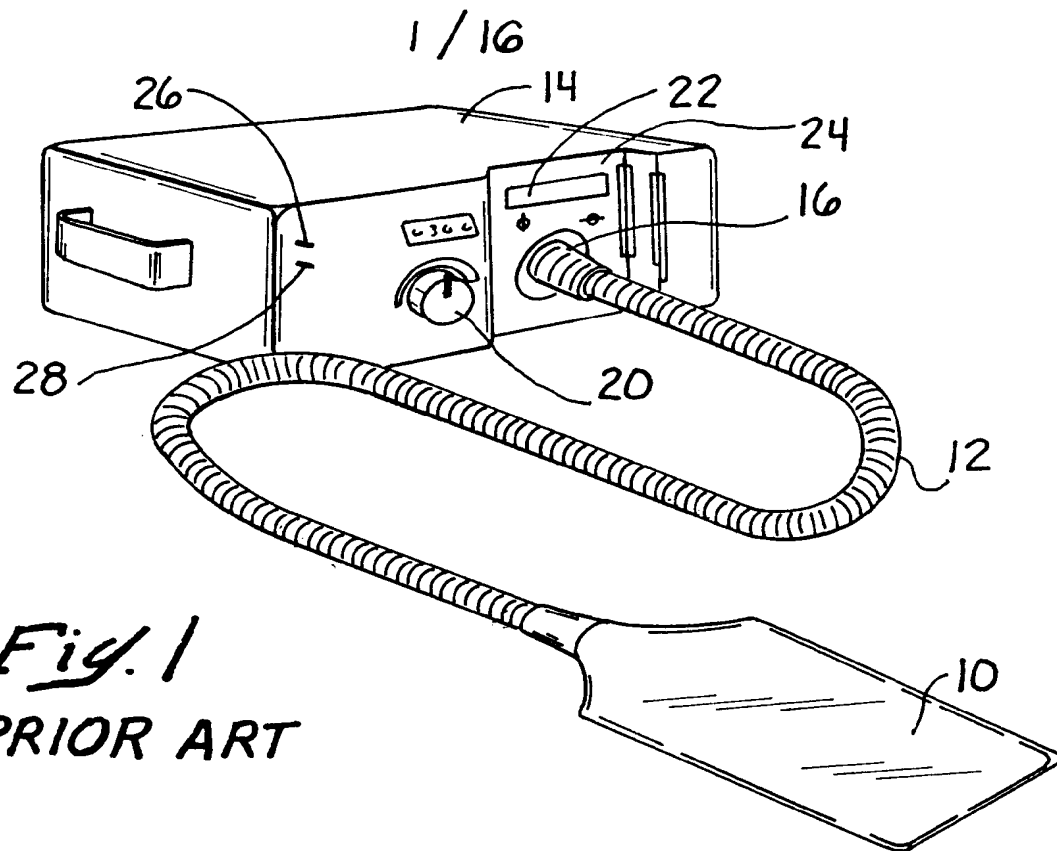
33. A wearable phototherapeutic illuminator for delivering light energy to the skin of a patient, comprising:

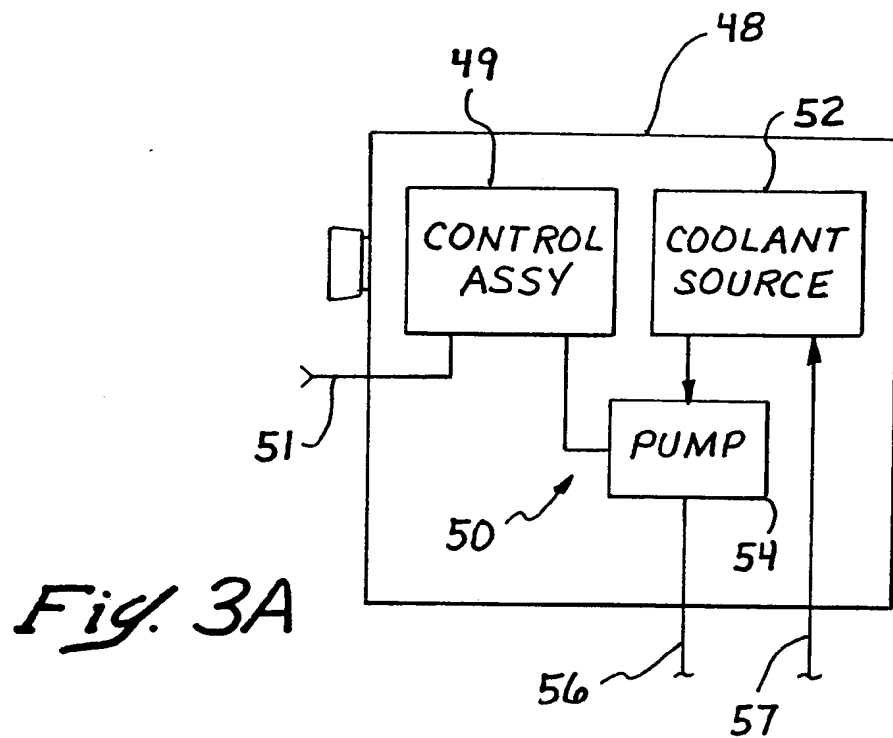
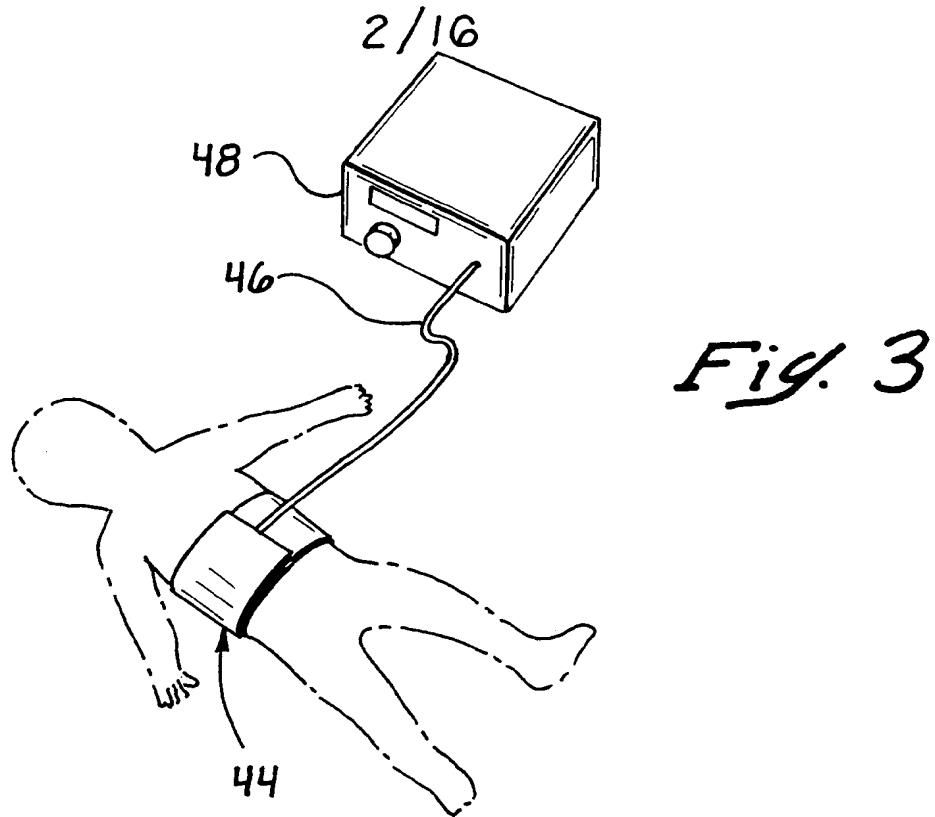
- a flexible substrate;
- 5 a plurality of light-generating sources disposed on the substrate; and
- a flexible, polymeric layer covering the light-generating sources, the layer permitting light energy to penetrate therethrough and adapted to substantially conform to the skin of a patient,
- 10 the layer diffusing the light emitted from the sources to result in a more uniform overall emittance, the illuminator being adapted to contact the skin of a patient.

15 34. The illuminator of claim 33, wherein the layer comprises a matrix with glass bubbles dispersed therein to diffuse the light emitted from the light-generating sources.

20 35. The illuminator of claim 33, wherein the layer comprises a matrix with titania dispersed therein to diffuse the light emitted from the light-generating sources.

25 36. The illuminator of claim 33, wherein the layer comprises an exterior surface adapted to contact the skin of the patient, the exterior surface having surface deformities to diffuse the light emitted from the light-generating sources.





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Fig. 4

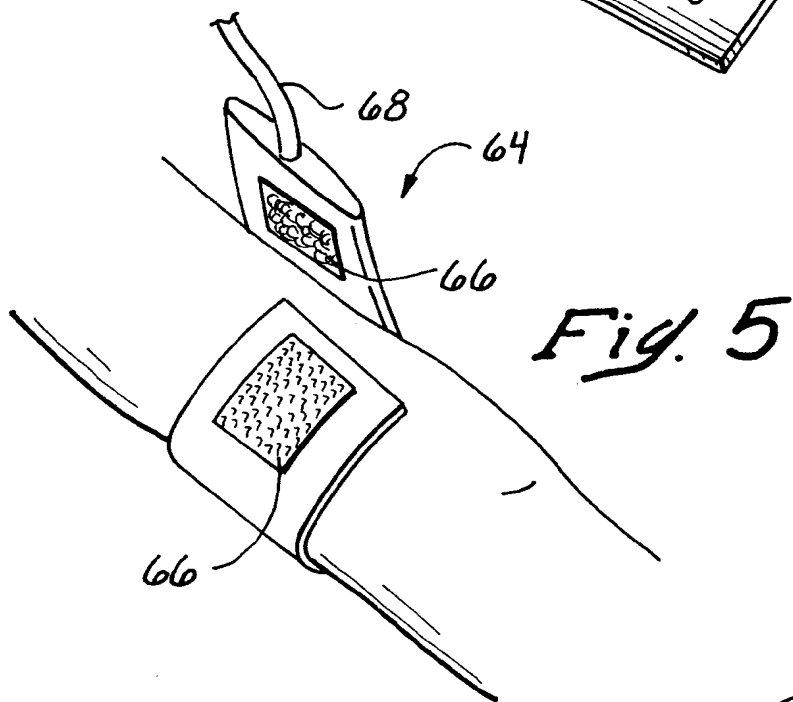
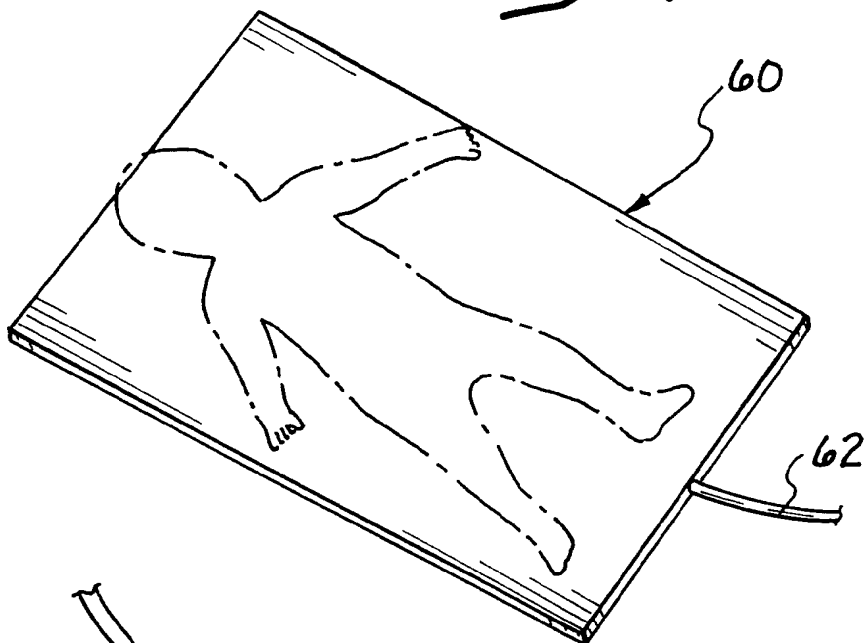
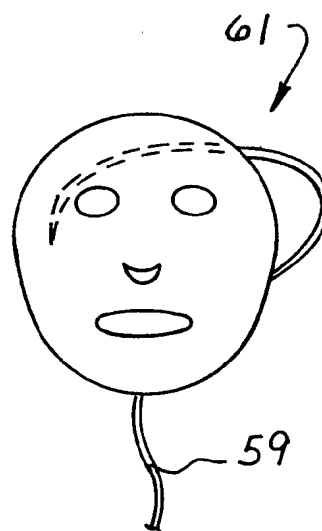
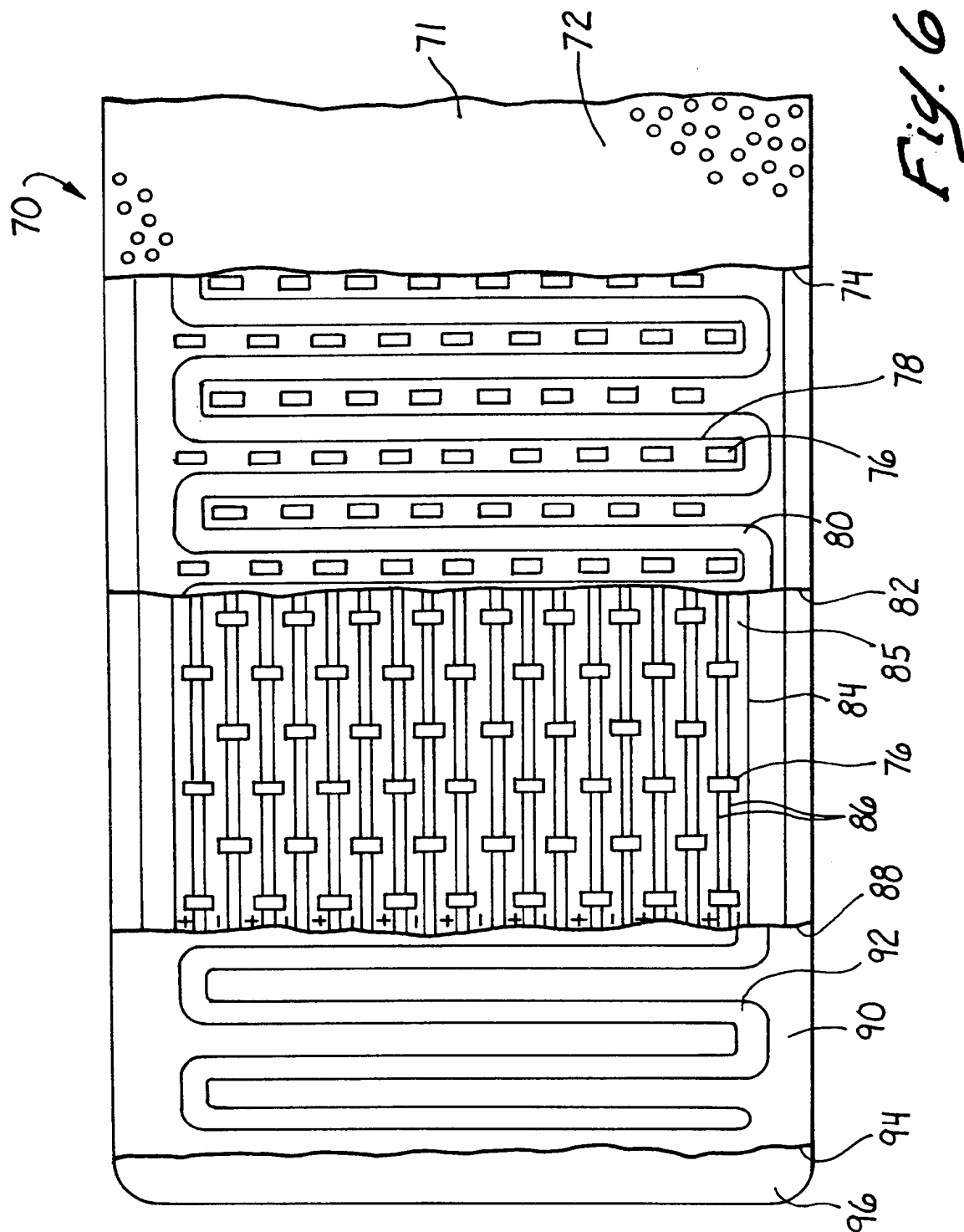


Fig. 5

Fig. 5A



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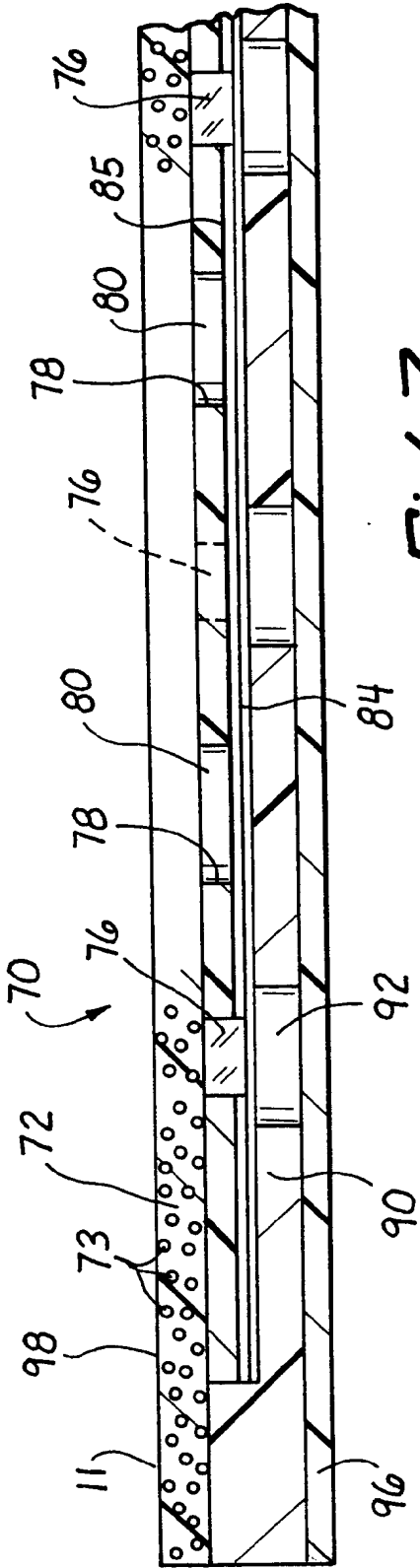


Fig. 7

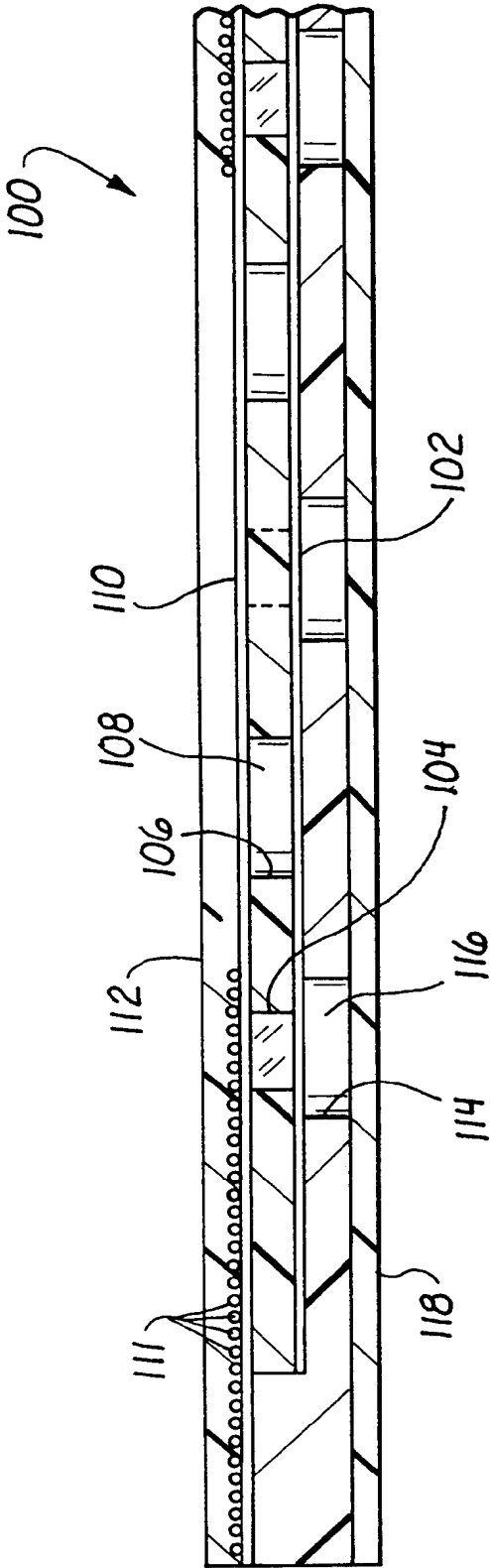
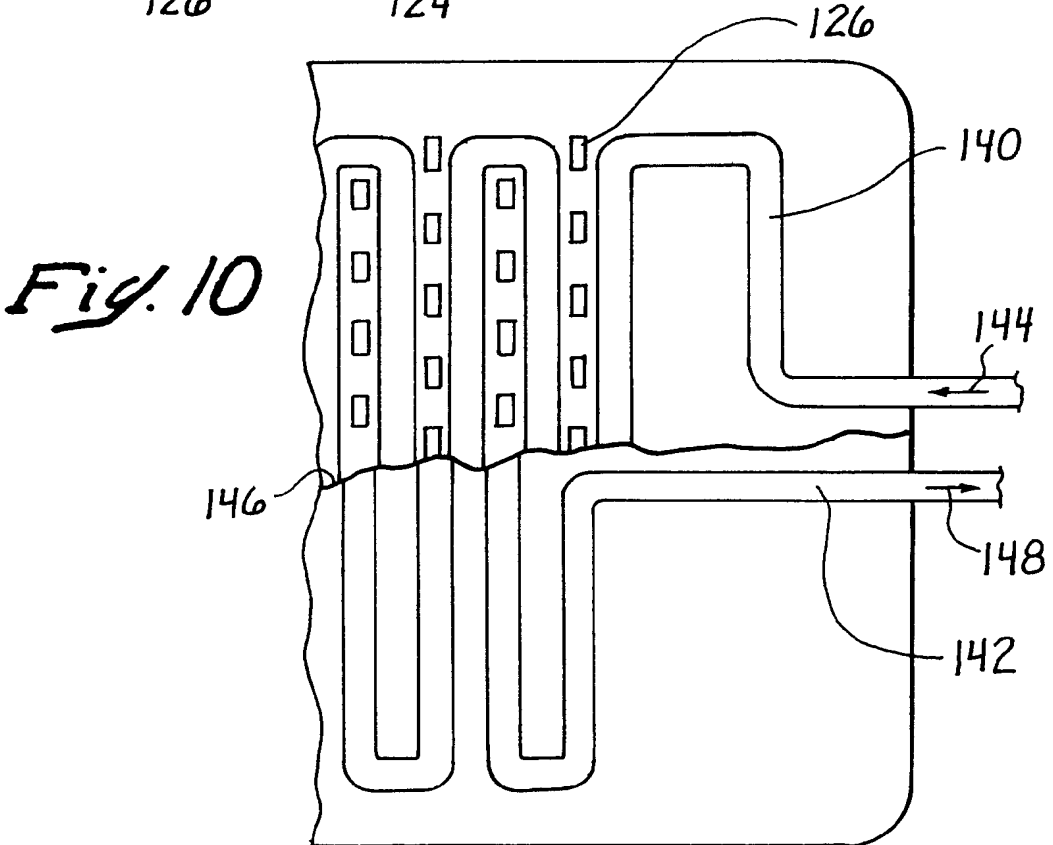
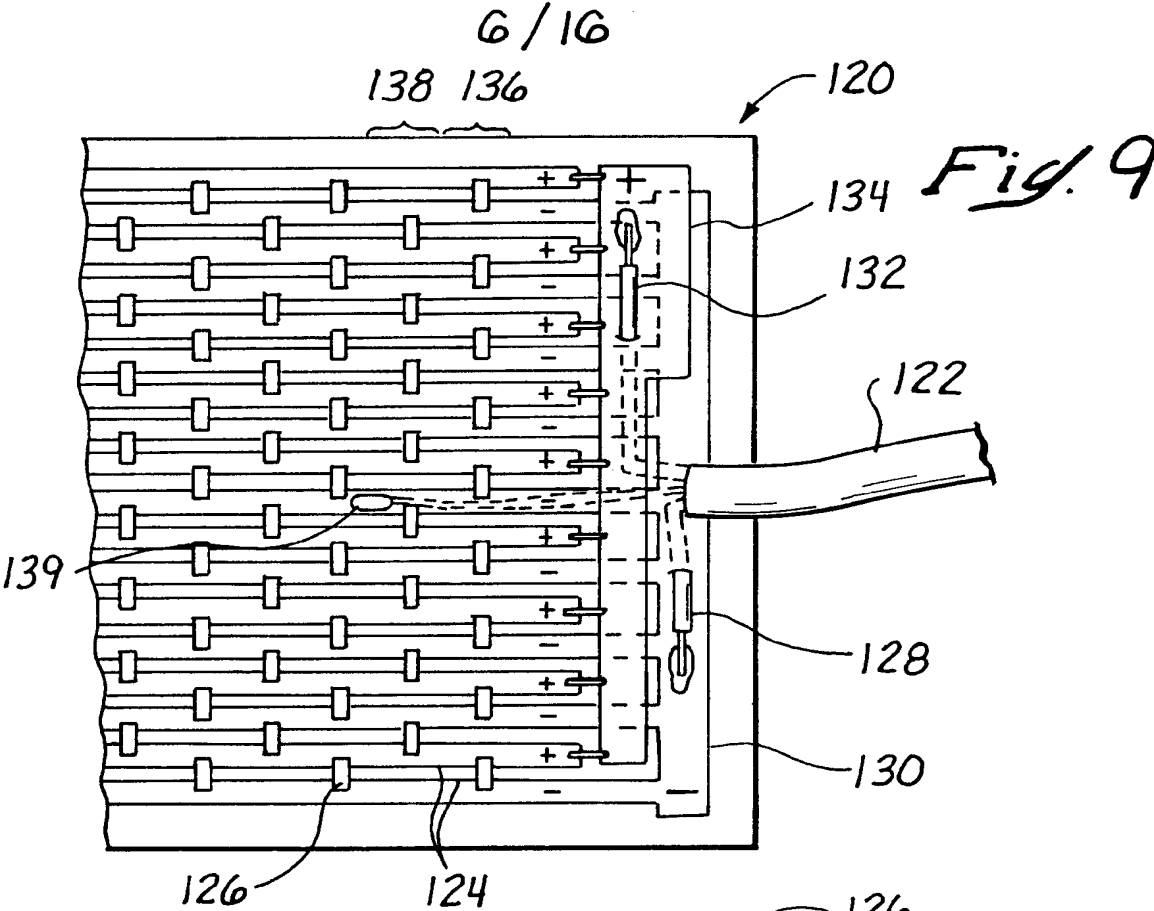


Fig. 8



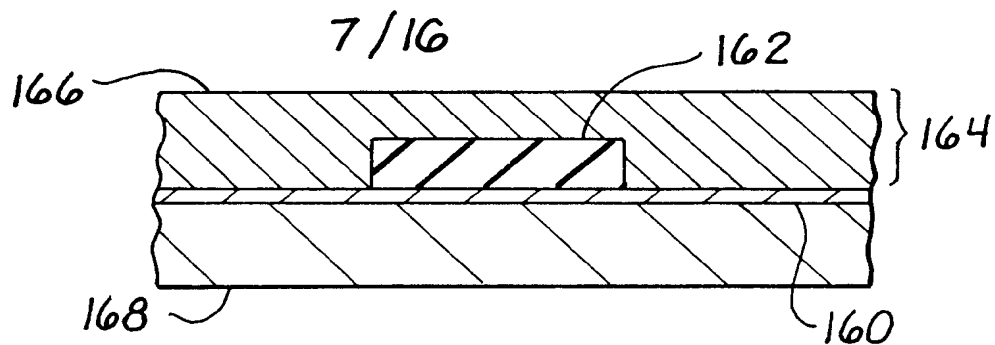


Fig. 11A

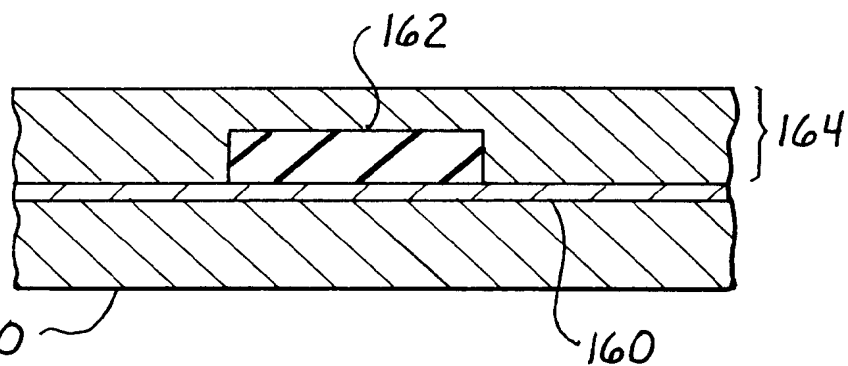


Fig. 11B

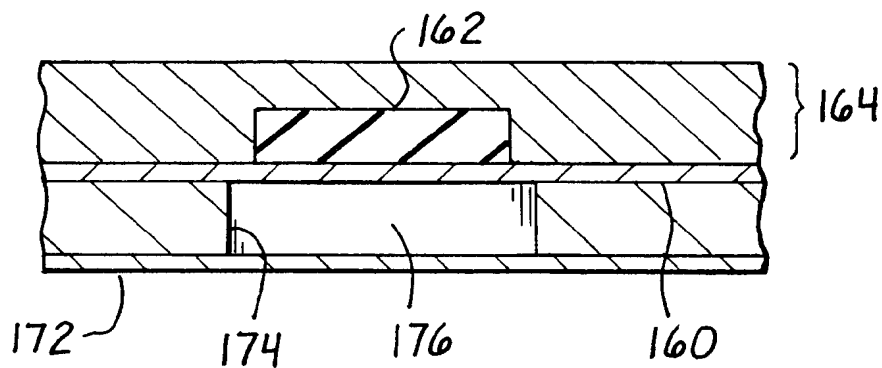


Fig. 11C

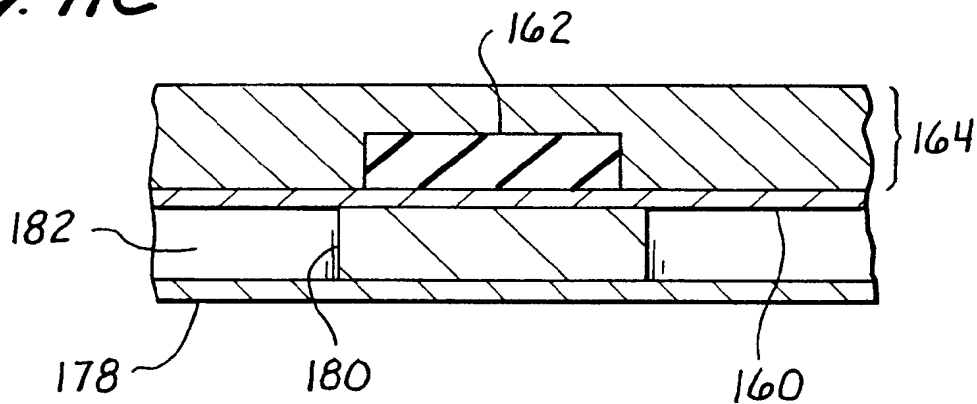


Fig. 11D

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Fig. 12A

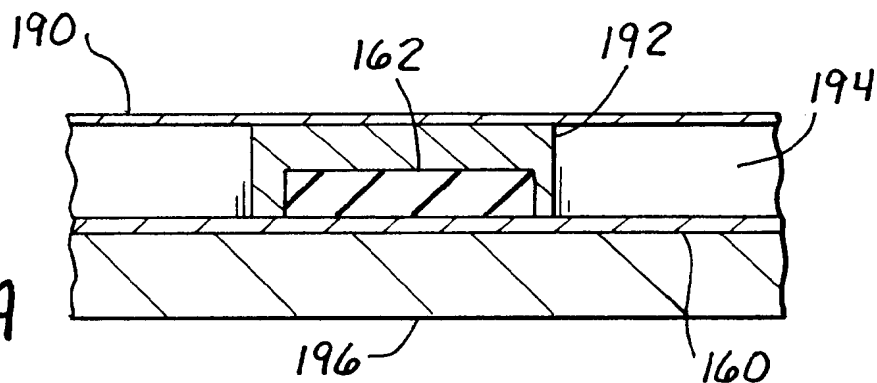


Fig. 12B

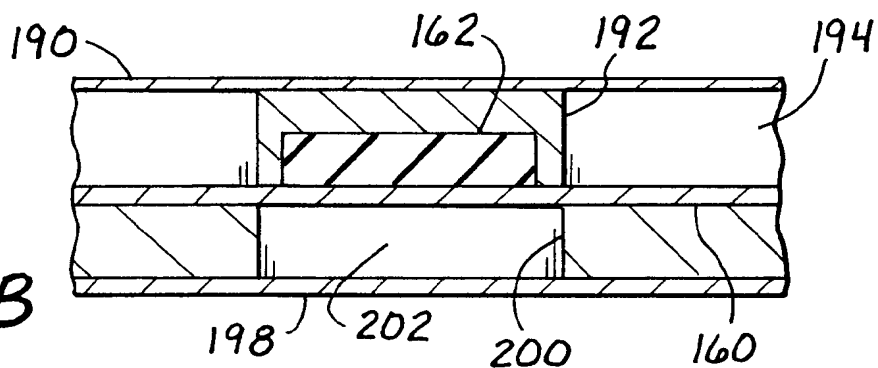


Fig. 12C

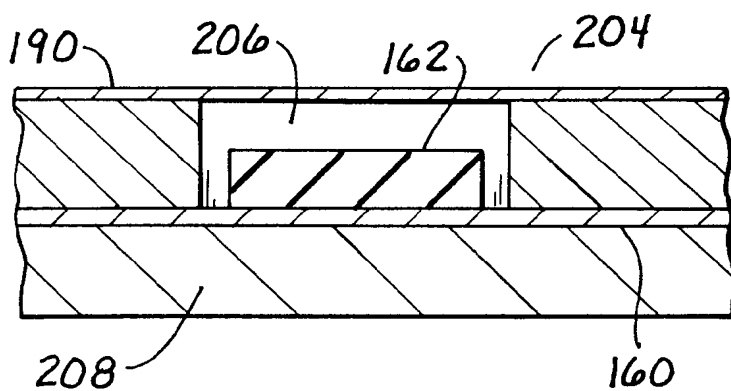
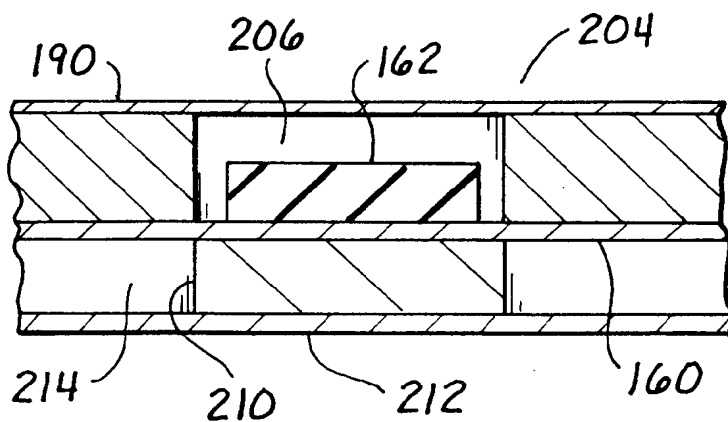
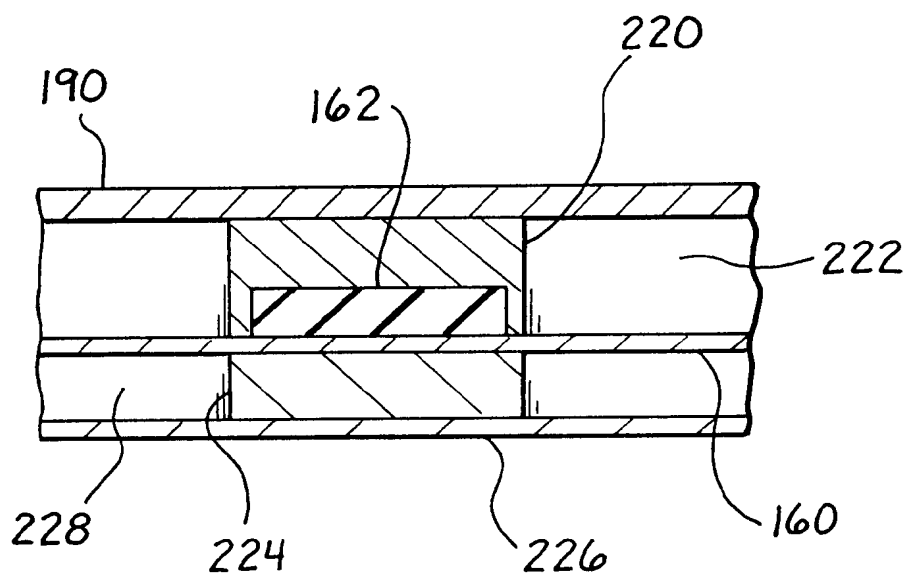
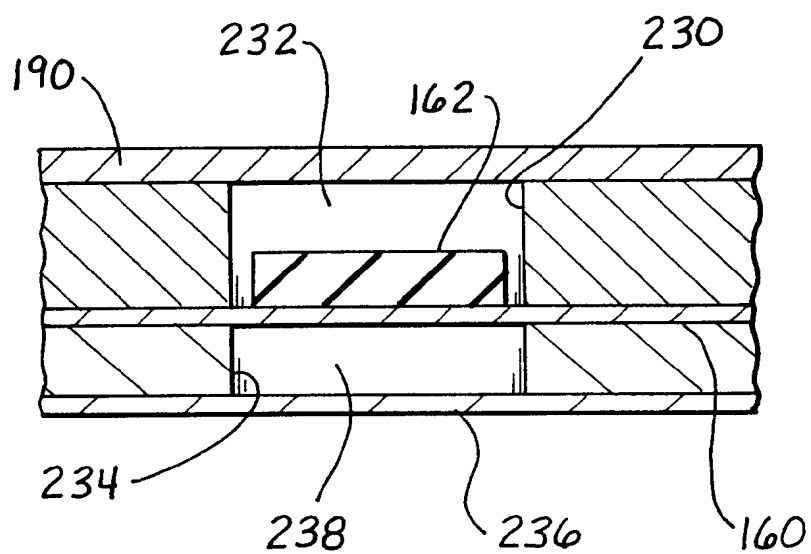
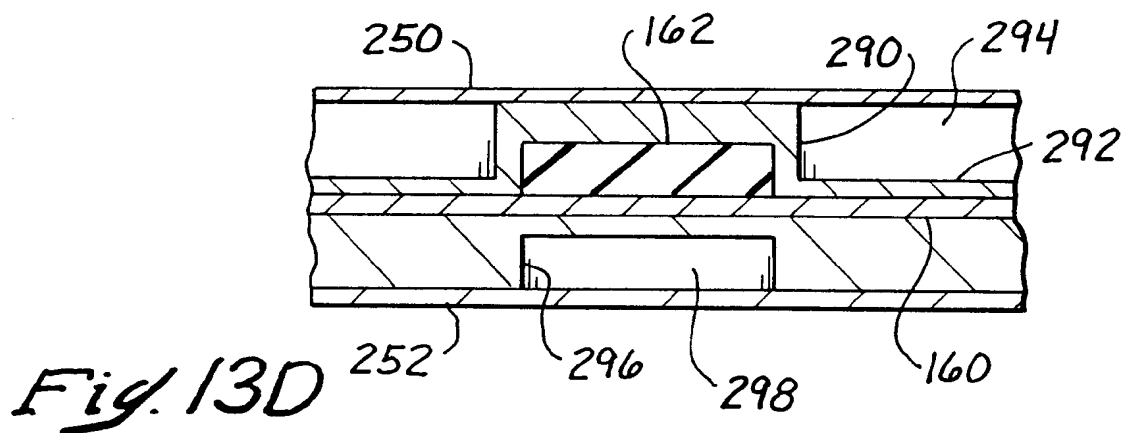
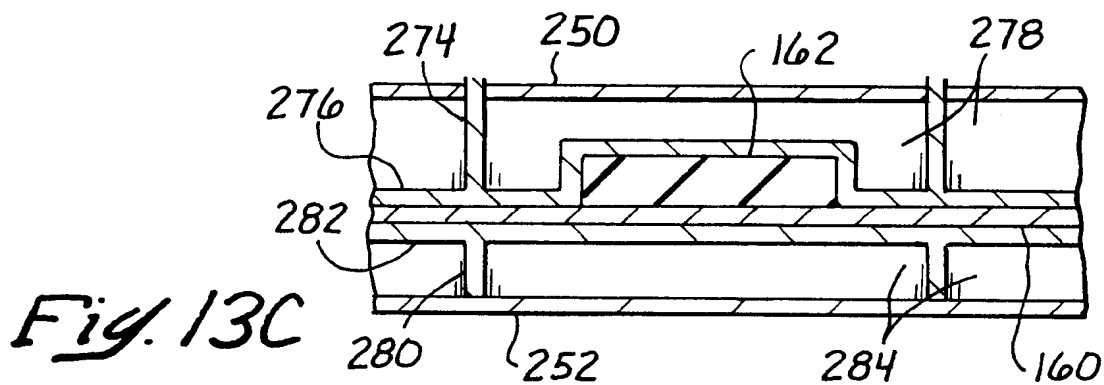
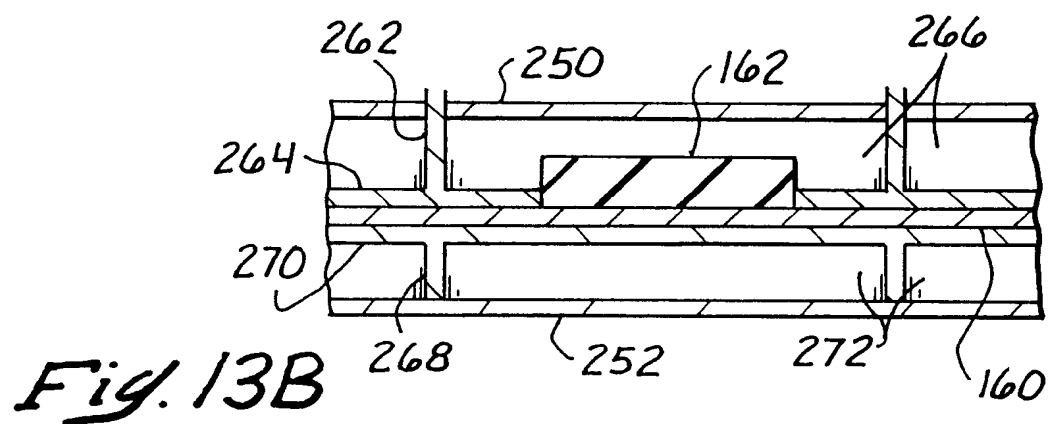
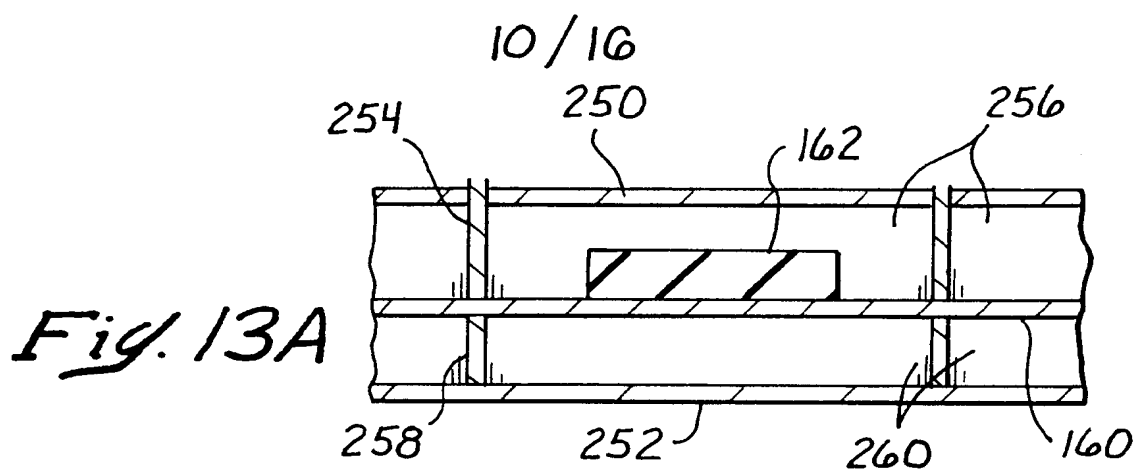


Fig. 12D



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*Fig. 12E**Fig. 12F*



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Fig. 14A

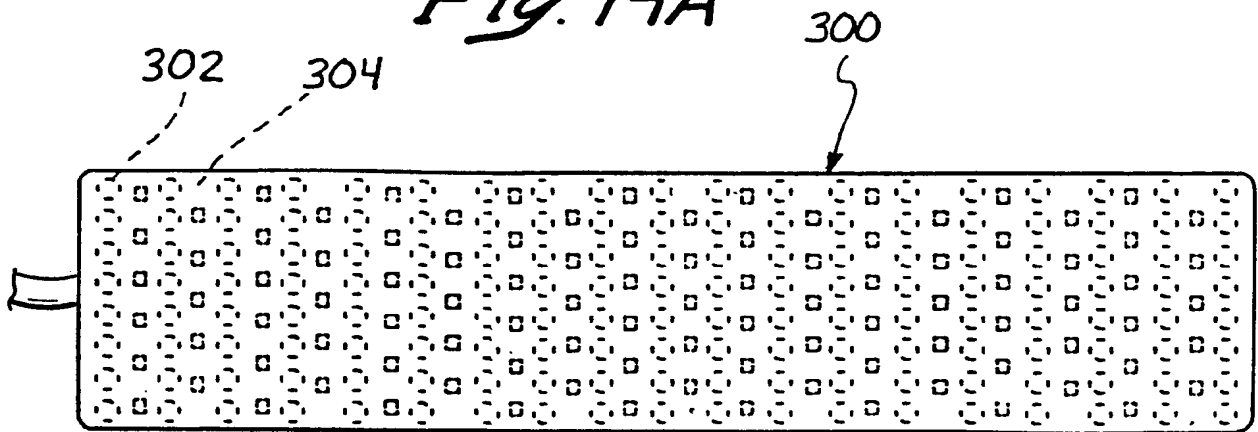


Fig. 14B

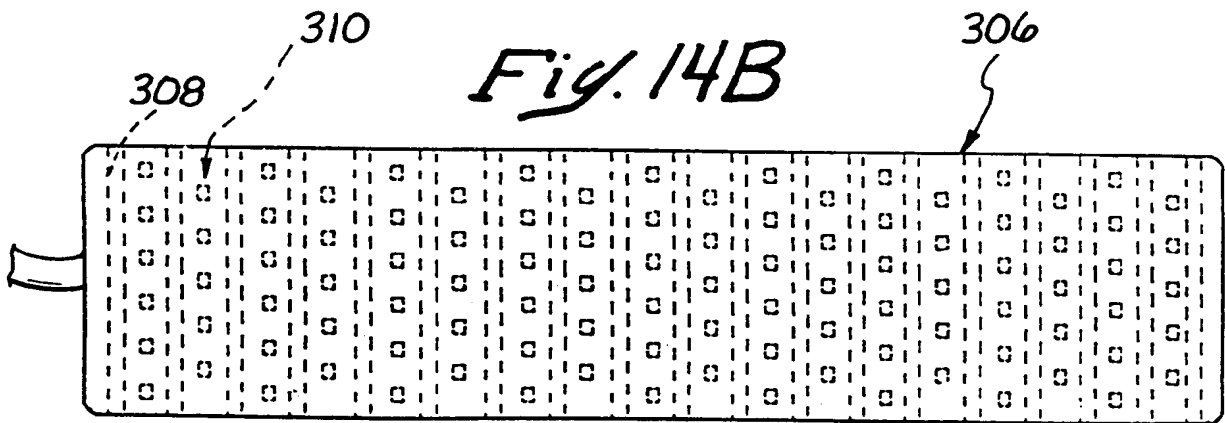
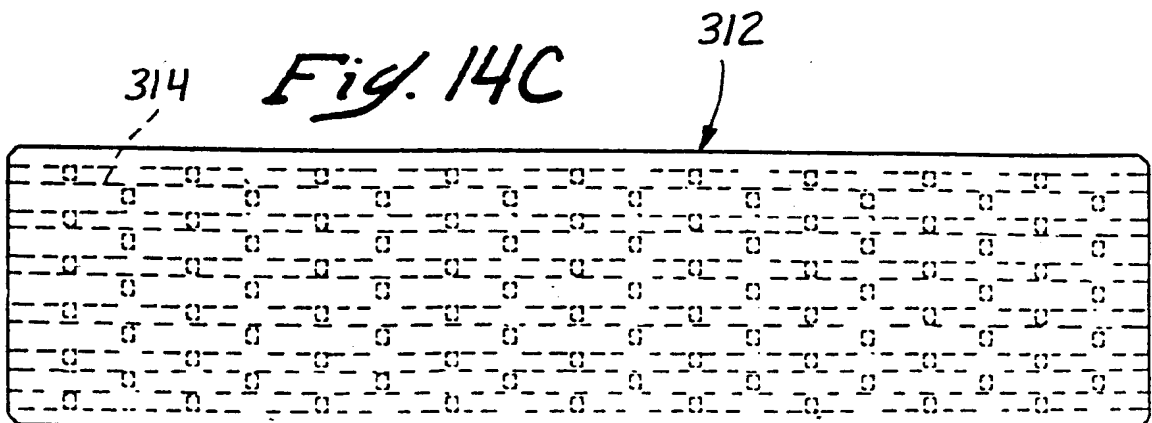
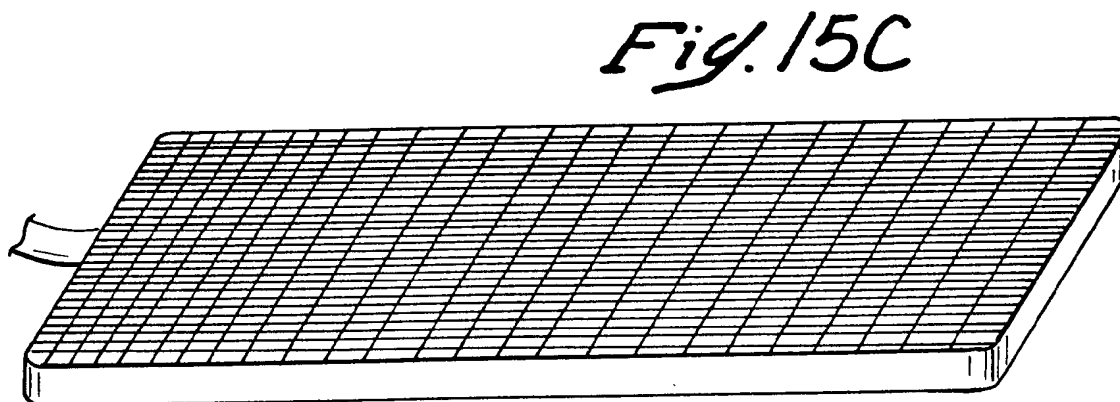
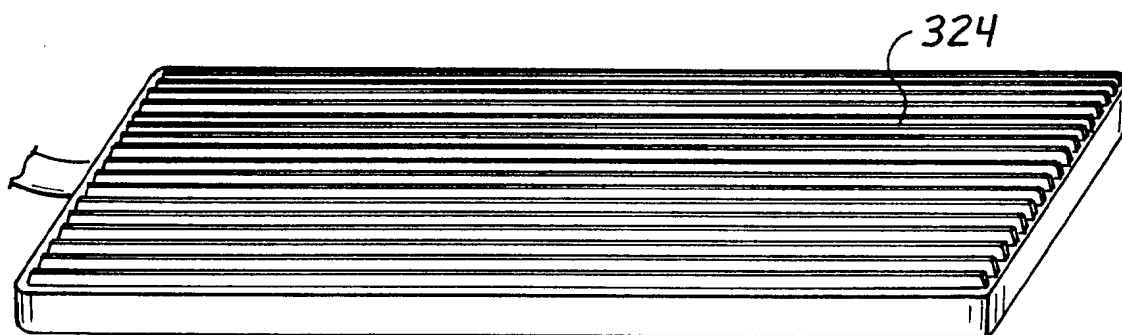
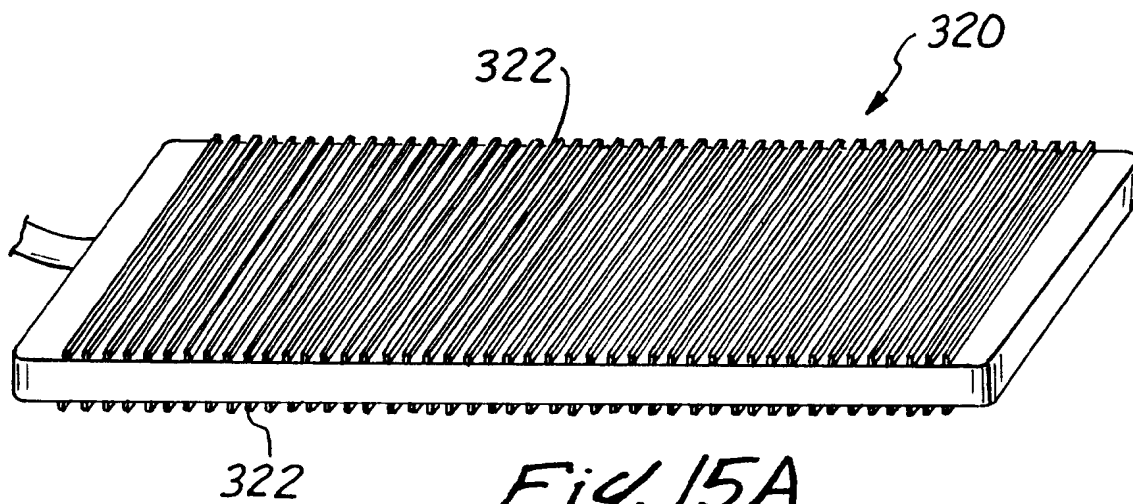


Fig. 14C



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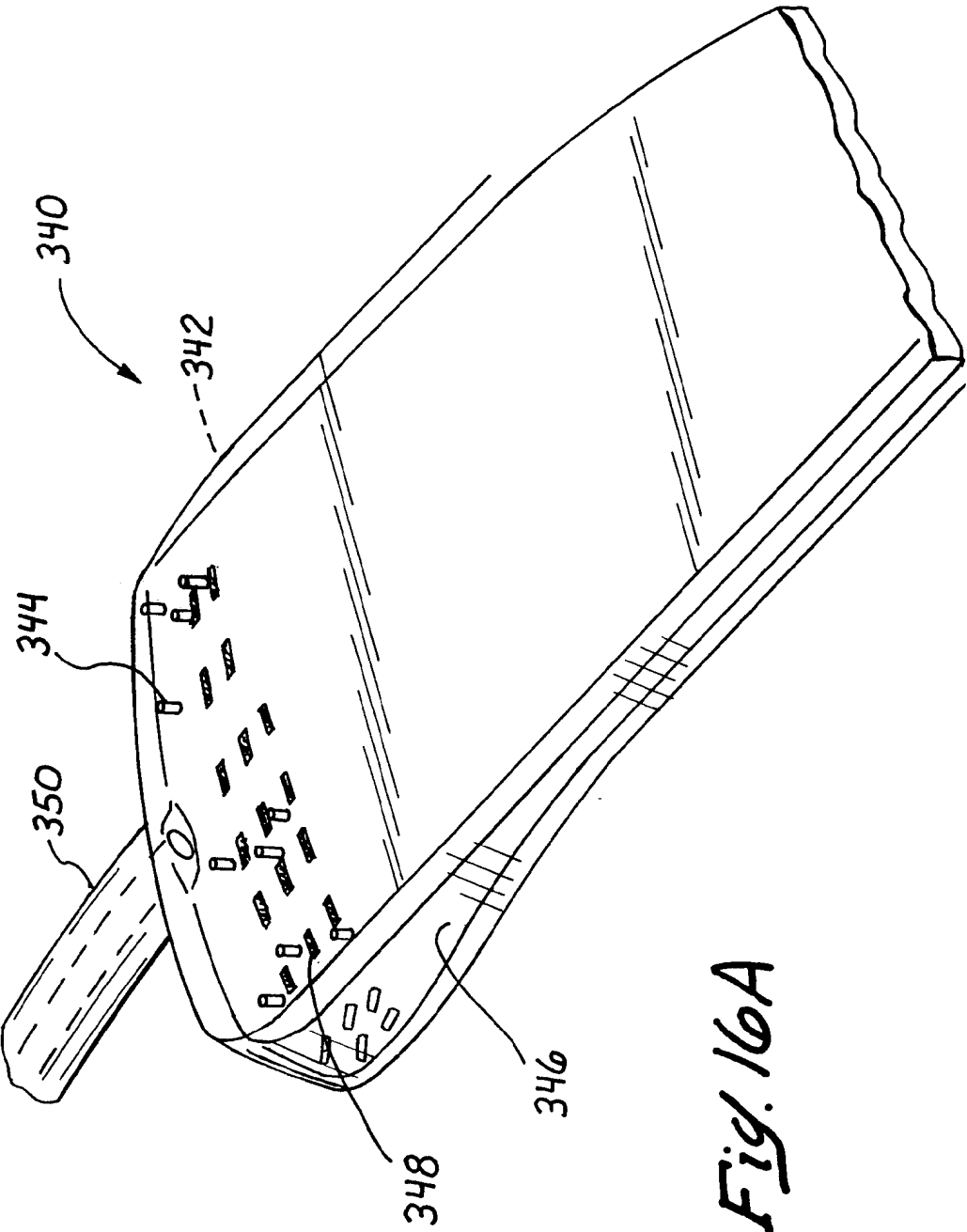
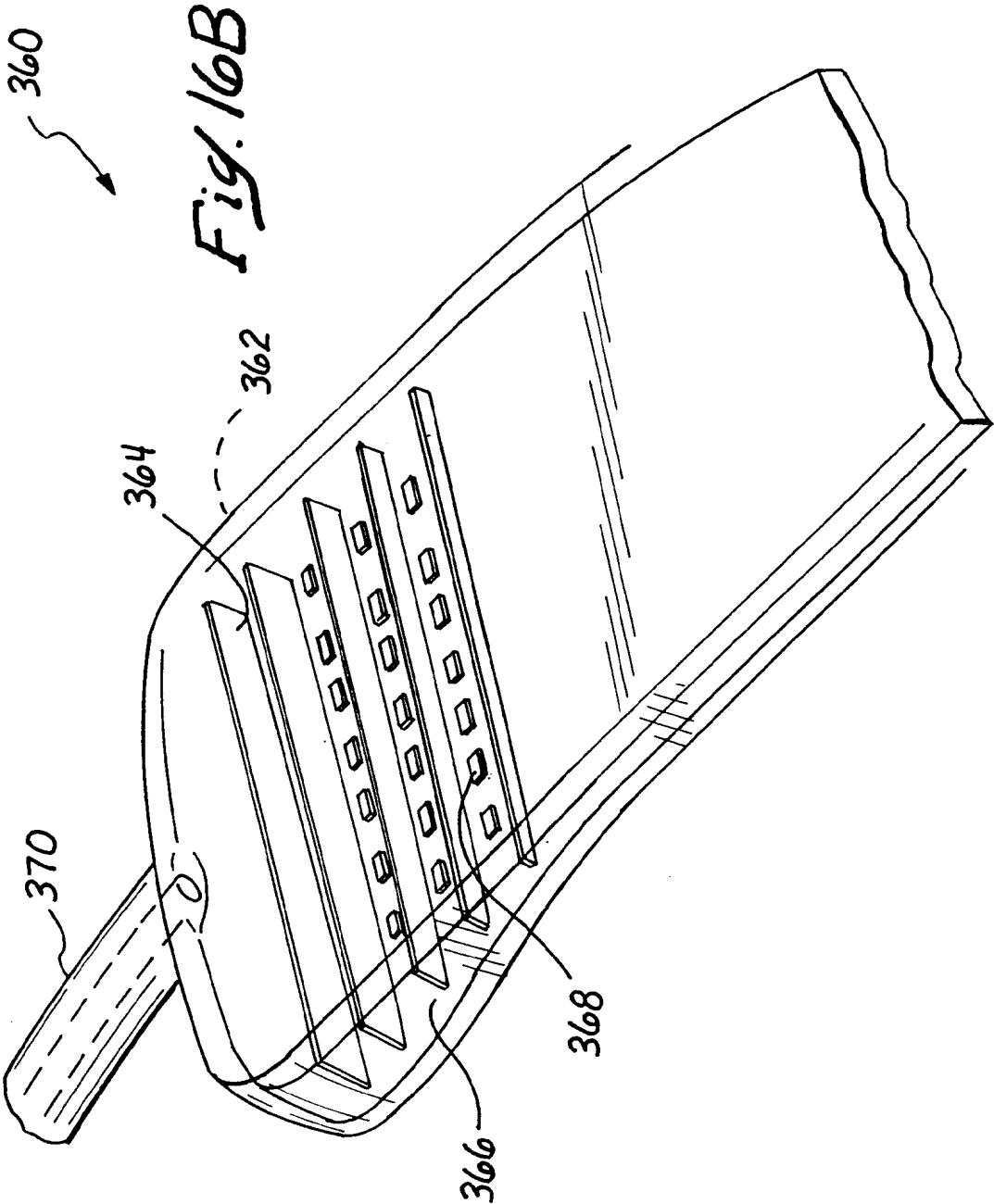
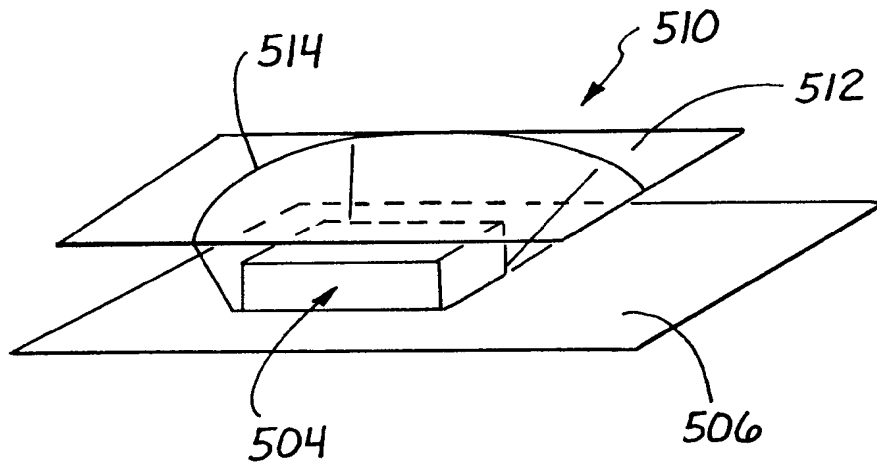
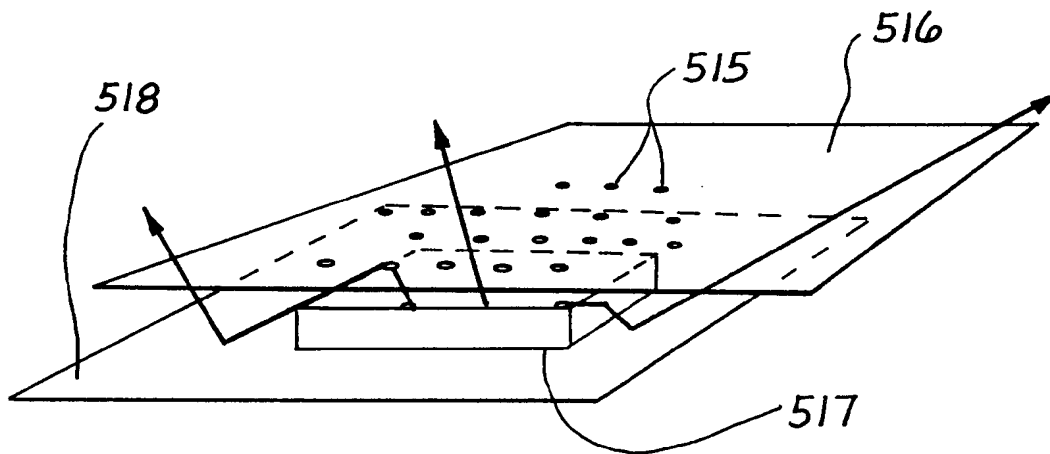


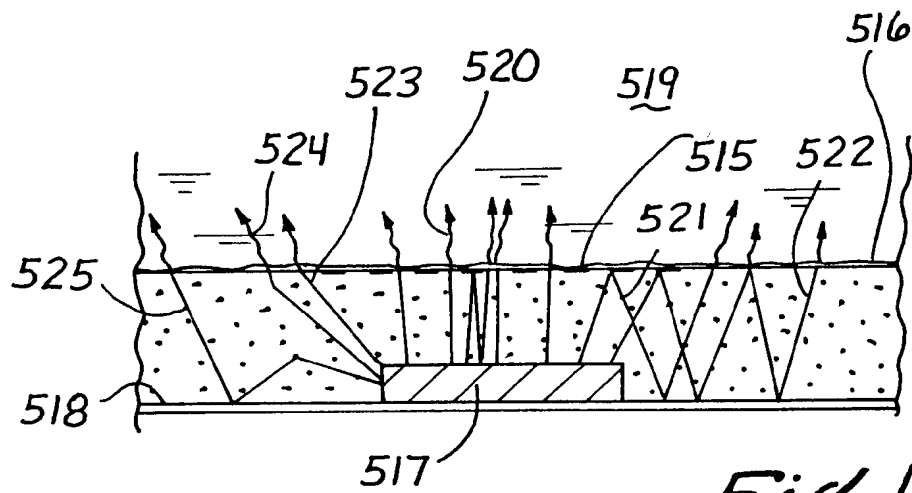
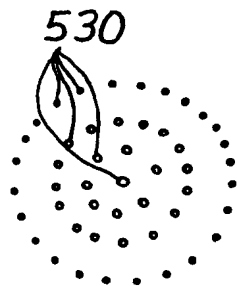
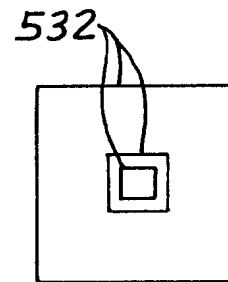
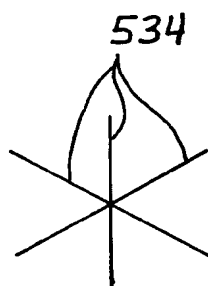
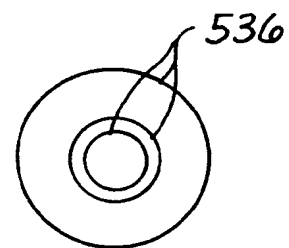
Fig. 16A



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*Fig. 17A**Fig. 17B*

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*Fig. 17C**Fig. 18A**Fig. 18B**Fig. 18C**Fig. 18D*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/22720

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61N 5/06

US CL : 606/9, 13; 607/88

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/9, 13; 607/88

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,616,140 A (PRESCOTT) 01 April 1997, entire document.	1-8, 11-19, 23-26, 28-34, 37
A	US 5,913,883 A (ALEXANDER et al.) 22 June 1999, entire document.	1-37
A	US 5,634,711 A (KENNEDY et al.) 03 June 1997, entire document.	1-37
A	US 5,800,479 A (THIBERG) 01 September 1998, entire document.	1-37

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search	Date of mailing of the international search report
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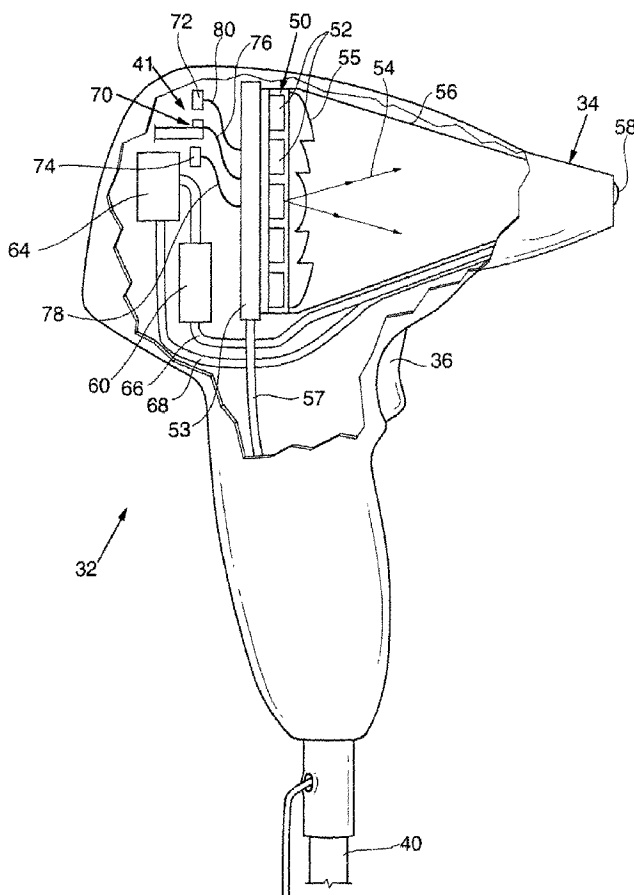
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AUTOMATIC FIRING APPARATUS AND METHODS FOR LASER SKIN TREATMENT OVER LARGE AREAS



(57) Abstract: Laser skin treatment apparatus includes a handpiece for delivering laser-radiation pulses from a laser to an area of skin being treated. The area being is larger than an area treatable in a single firing of the laser. The larger area is treated by treating adjoining sub-areas within the larger area by repeated firings of the laser. The laser is fired automatically depending on the position of the handpiece in the larger area. Several arrangements for determining the position of the handpiece are disclosed. These include optical detection by the handpiece of indicia drawn on the skin being treated; optical, magnetic, or mechanical detection of indicia on a separate guide for the handpiece or on a roller attached to the handpiece; and detection by determining time of travel of signals from a transponder in the handpiece to a fixed reference plane.



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**AUTOMATIC FIRING APPARATUS AND METHODS FOR
LASER SKIN TREATMENT OVER LARGE AREAS**

5 TECHNICAL FIELD OF THE INVENTION

 The present invention relates in general to
apparatus for laser skin treatment, such as
depilation. The invention relates in particular to
an automatic repeat firing system for laser skin
10 treatment apparatus which, in a single firing, can
treat only a relatively small sub-area of an area of
skin to be treated.

DISCUSSION OF BACKGROUND ART

 In laser dermatological treatment operations
15 such as depilation, an area of skin to be treated may
often be much greater than the area which can be
treated by a single firing of laser apparatus.
Typical apparatus for laser treatment includes a
handpiece for delivering laser radiation from a laser
20 to skin being treated. The laser may be remote from
the handpiece with the laser radiation being
delivered to the handpiece via an optical fiber or
articulated arm. Alternatively, the laser radiation
may be provided by a diode-laser array incorporated
25 in the handpiece. A handpiece is often furnished
with a cooled window which is placed in contact with
the skin, laser radiation being delivered to the skin
through the cooled window.

 Treatment of a large area of skin is typically
30 accomplished by an operator manually firing the laser
apparatus, with the handpiece located in one position
on the area of skin being treated, then moving the

handpiece to another position in the treatment area and manually firing the laser apparatus again. One disadvantage of this method is that it can be difficult to precisely and contiguously locate treated sub-areas of the total area being treated such that no sub-area is left untreated and no overlapping of treated sub-areas occurs. Another disadvantage of this method is that time taken to relocate the handpiece from a treated sub-area to an adjacent untreated sub-area can prolong the treatment operation. This, in turn, can lead to an increased cost of the operation. The apparatus and method of the present invention is intended to overcome these disadvantages.

SUMMARY OF THE INVENTION

The present invention is directed to a method of treating an area of skin with a laser by delivering a series of laser-radiation pulses to the skin. Each of the laser pulses treats a sub-area of the area to be treated.

In one aspect of the present invention, a laser is provided which, on being fired, generates a pulse of laser-radiation. A handpiece is provided and arranged for delivering a pulse of laser-radiation from the laser to the skin being treated.

While the handpiece is being moved over the skin being treated, the location of the handpiece in the area of skin being treated is electronically determined, and the laser is automatically fired when the electronically determined location corresponds to a sub-area to be treated.

The terminology "automatically fired" here means that as the firing of the laser is electronically triggered by the electronic position determination without operator intervention other than moving of

the handpiece. The terminology "laser" means a laser resonator including a gain medium (which may be a diode-laser or array of same) and those electrical and electronic circuits needed to power the laser and to switch or modulate the laser to provide the laser-radiation pulses.

In one embodiment of the present invention the location determining step includes providing a plurality of regularly spaced indicia on or adjacent the area of skin being treated. At least one sensor is provide on the handpiece and arranged to detect passage of the handpiece by one or more of the indicia as the handpiece is moved over the skin being treated. The automatic firing is triggered by the passage of the handpiece by one or more of the indicia. The indicia may be graphic indicia, magnetic indicia, or mechanical indicia.

In one example of this preferred embodiment of the present invention, the indicia are graphic (optically detectable) indicia. The sensor includes a light-source arranged to direct light onto the skin being treated such that the thus directed light is scattered by the skin being treated. The sensor includes one or more light detectors arranged to detect the light scattered by the skin. The graphic indicia are equally-spaced parallel lines drawn on the area of skin being treated in a medium which is opaque to the wavelength of light emitted by the light-source and transparent to the wavelength of said pulse of laser radiation. Passage of the handpiece by any one of the indicia (crossing any one of the lines) results in a reduction in the scattered light detected by the detector. The reduction in scattered light indicating that one of said indicia has been passed, i.e., a line has been crossed.

In another embodiment of the present invention the location determining step comprises providing a roller on the handpiece, the roller being arranged to contact the skin being treated and rotate in response to the handpiece being moved over the skin being treated. The roller has a plurality of regularly spaced indicia thereon. At least one sensor is provided on the handpiece. The sensor is arranged to detect passage by the sensor of one or more of the indicia as the roller rotates. The automatic firing is triggered by the passage by the sensor of one or more of the indicia.

The indicia on the roller may be radially extending lines on a side of the roller or longitudinally extending lines on a cylindrical surface of the roller. The indicia in either case may be graphic (optically detectable) indicia or magnetic (magnetically detectable) indicia. In one variation of this embodiment, indicia can be omitted from the roller and the roller axially connected to a shaft encoder, the shaft encoder providing signals used for the electronic position determination.

In yet another embodiment of the present invention, the location determining step comprises providing a screen adjacent the skin being treated. A transponder is provided on the handpiece. The transponder is arranged to emit a regular train of signal-pulses toward the screen such that the signal-pulses are incident thereon and a return-pulse corresponding to each of the incident signal-pulses returns to the handpiece. A receiver is provided on the handpiece for receiving the return pulses. An elapsed time between emitting a signal-pulse and receiving a corresponding return-pulse is determined. The elapsed time is representative of the location of the handpiece.

The signal-pulses are preferably ultrasonic pulses. However, the use of other forms of signal pulses is possible, for example optical pulses or radar pulses.

5 In still another embodiment of the present invention the location determining step also includes providing a transponder on the handpiece. The transponder is arranged to emit a regular train of signal-pulses each thereof in diverging beam. At
10 least two spaced-apart receivers are provided. The receivers are located in a position remote from the handpiece, within the divergence of the beam, for receiving said signal pulses. Based on the spacing of the receivers and an arrival time of the signal
15 pulses at the receivers, the location of the handpiece is determined in at least length and width dimensions of the area of skin to be treated. For an area of skin to be treated which is contoured, three spaced-apart receivers may be provided, and the
20 location of said handpiece in the area of skin to be treated determined in length width and height dimensions.

 In another aspect of the present invention, the handpiece may be equipped with a skin contact-sensor
25 for determining whether or not the handpiece is in contact with skin being treated. This is useful in laser skin treatments wherein laser radiation is delivered to the skin via a lens or transparent body (applicator) incorporated in the handpiece and in
30 contact with the skin for promoting efficient coupling of laser radiation into dermal layers.

 In one preferred embodiment of skin-contact sensing in accordance with the present invention, a light-source is provided having an exit-aperture
35 thereof on the handpiece. The exit-aperture is configured to be in contact with the skin being

treated when the applicator is in contact with the skin being treated. Light from said light-source is delivered via said exit-aperture thereof such that, when the applicator is in contact with the skin, light delivered the said exit-aperture is transported laterally through the skin via volume scattering of the light. A detector is provided having a receiving-aperture on the handpiece proximate the light-source exit-aperture. The output of the detector is monitored. The monitored detector-output is interpreted as an indication that the applicator of the handpiece has made or lost contact with the skin being treated.

The above-described contact skin contacting method is not limited to a handpiece delivering laser-radiation for skin treatment but is applicable to handpiece delivering electromagnetic radiation (for skin treatment) from an incoherent source such as a flashlamp. An above-described sensor for detecting graphic indicia may be configured to additionally function as a skin sensor for implementing the above-described skin-contact sensing method.

Preferred embodiments of the present invention are described in detail hereinbelow with reference to a laser hair removal apparatus using an array of diode-lasers. Automatic firing arrangements in accordance with the present invention are neither limited to apparatus including diode-lasers, nor limited to hair removal apparatus. Those skilled in the art will recognize that automatic firing principles of the present invention are applicable to laser apparatus including other laser types, for example, solid-state lasers, to apparatus wherein treatment light is provided by an incoherent source of electromagnetic radiation such as a flashlamp, and

to other laser skin treatments, for example, treatment of vascular lesions such as "port wine" stains.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The accompanying drawings, which are incorporated in and constitute a part of the specification, schematically illustrate a preferred embodiment of the present invention, and together with the general description given above and the
10 detailed description of the preferred embodiment given below, serve to explain the principles of the invention.

FIG. 1 is a perspective view schematically illustrating a first preferred embodiment of laser
15 treatment apparatus in accordance with the present invention having a first handpiece including a chilled tip and having a position sensor located therein, the handpiece being movably connected to a control console for controlling operating parameters
20 of the apparatus.

FIG. 2 is a rear elevation view of the handpiece of FIG. 1 schematically illustrating the handpiece being moved in a direction orthogonal to a regular grid of parallel lines drawn on an area of skin being
25 treated.

FIG. 3 is a partially-cutaway side elevation view of the handpiece of FIG. 1 schematically illustrating a light-source and photodetectors of the position sensor for respectively sending light to and
30 receiving light from optical apertures in the tip of the handpiece.

FIG. 4 is a partial front elevation view of the handpiece of FIG. 1 schematically illustrating details of the chilled tip of the handpiece and optical apertures of the sensor therein.

5 FIG. 5 is a partial cross-section view of the handpiece of FIG. 1 seen generally in the direction 5-5 of FIG. 4 and schematically illustrating further details of the position sensor in the handpiece.

10 FIG. 6 is a rear elevation view schematically illustrating a second handpiece in accordance with the present invention arranged for automatic firing in both longitudinal and lateral directions of motion thereof.

15 FIG. 7 is a partial front elevation view of the handpiece of FIG. 6 schematically illustrating details of the chilled tip of the handpiece and optical apertures of four position sensors therein.

20 FIG. 8 is a partial rear elevation view schematically illustrating a third handpiece in accordance with the present invention arranged for automatic firing by sensing crossings of lines on a ruled guide-strip placed, rulings uppermost, in contact with skin being treated.

25 FIG. 9 is a front elevation view of the handpiece of FIG. 8 schematically illustrating details of position sensors for detecting the line-crossings.

30 FIG. 10 is a partial side elevation view of the handpiece of FIG. 8, schematically illustrating

further details of one of the position sensors for detecting the line-crossings.

FIG. 11 is a partial plan view of the handpiece of FIG. 8 seen in the direction 11-11 of FIG. 9 and schematically illustrating further details of the position sensors for detecting the line-crossings and further details of the ruled guide-strip of FIG. 8.

FIG. 12 is a partial side elevation view schematically illustrating a fourth handpiece in accordance with the present invention arranged for automatic firing by sensing crossings of lines on a ruled guide-strip placed on edge, rulings facing sideways, in contact with skin being treated.

FIG. 13 is a front elevation view schematically illustrating further details of the handpiece of FIG. 12 including a side-looking position sensor for sensing the line-crossings.

FIGS. 14 and 15 are partial side elevation views schematically illustrating opposite sides of a fifth handpiece in accordance with the present invention arranged for automatic firing by sensing crossings of radial lines on wheel attached thereto, the wheel arranged to contact skin being treated.

FIGS. 15A and 15B are, respectively, side and front elevation views schematically illustrating details of a skin-contact sensor head for the handpiece of FIGS. 14 and 15.

FIG. 15C is a front elevation view schematically illustrating details of an alternative skin-contact sensor head for the handpiece of FIGS. 14 and 15.

FIG. 15D is a graph schematically illustrating detector output as a function of distance from various surfaces of a skin-contact sensor head in accordance with the arrangement of FIG. 15C.

5 FIG. 16 is a plan view from above schematically illustrating further details of the handpiece of FIGS. 14 and 15.

10 FIG. 17 is a partial side elevation view schematically illustrating opposite sides of a sixth handpiece in accordance with the present invention having a wheel attached thereto and connected to a shaft encoder, the wheel arranged to contact skin being treated and the handpiece arranged for automatic firing responsive to signals provided by
15 the shaft encoder.

20 FIG. 18 is a plan view of the handpiece of FIG. 17 seen generally in the direction 18-18 of FIG. 17 and schematically illustrating further details of the wheel and a shaft-encoder and bearing housing on the tip of the handpiece.

25 FIG. 19 a side elevation view schematically illustrating a ninth handpiece in accordance with the present invention, having a detachable housing including a roller cooperative with a position sensor.

FIG. 20 is a perspective view schematically illustrating the detachable housing and roller of FIG. 19.

FIG. 20A is a perspective view schematically illustrating an alternative form of roller for the handpiece of FIG. 19.

5 FIG. 21 is a plan view from below schematically illustrating the handpiece of FIG. 19 without the detachable housing and showing a vertically-oriented position sensor head for sensing rotation of the roller of FIG. 20.

10 FIG. 22 is a perspective view schematically illustrating a seventh handpiece in accordance with present invention, including a transponder, for sending a signal to a screen located proximate a patient being treated, and a receiver for receiving an echo of the signal from the screen for determining
15 the position of the handpiece in one dimension relative to the patient.

 FIG. 23 is a perspective view schematically illustrating an eighth handpiece in accordance with present invention, including a transponder for
20 sending a signal to three direction sensitive detectors proximate a patient being treated, signals from the detectors being used for determining the position of the handpiece in at least two dimensions relative to the patient.

25 DETAILED DESCRIPTION OF THE INVENTION

 Turning now to the drawings, wherein like features are designated by like reference numerals, FIG. 1 depicts a first preferred embodiment of laser skin treatment apparatus 30 in accordance with the
30 present invention. Apparatus 30 includes a handpiece 32 including a diode-laser array (not shown in FIG. 1) for providing laser radiation for treatment. The diode-laser array is alternatively referred to

hereinafter simply as the laser. The diode-laser array emits at a wavelength between about 790 and 830 nanometers (nm). This wavelength range should not be construed, however, as limiting the present invention.

In a tip 34 of handpiece 32 are located optical apertures of a position sensor incorporated in the handpiece. The apertures and other components of the position sensor are not shown in FIG. 1 but are described in detail further hereinbelow. The handpiece is activated by a trigger 36.

Apparatus 30 includes a control console 38. Control console 38 includes, inter alia, power-supplies, a water-supply and control electronics for components of handpiece 32. The control electronics and power and water supplies are connected to handpiece 32 via an umbilical sheath 40. When not in use, handpiece 32 may be "parked" in a receptacle 42 in control console 38. The operating sequence and treatment parameters for the apparatus are controlled from a touch-screen display 43.

Referring now to FIG. 2, in one preferred method of operating apparatus 30, a grid 44 of equally-spaced parallel lines 46 is drawn on skin 48 being treated. The grid preferably covers the entire area of skin on which treatment is desired. Lines 46 are preferably spaced apart by a distance equal to a linear dimension of the area treatable in a single firing of the laser or a sub-multiple of that dimension. Preferably, the area treatable in a single laser firing is made square, or at least rectangular, in which case the spacing of lines 46 is made equal to the width or length of the area or some sub-multiple thereof. Handpiece 32 is moved in a direction orthogonal to lines 46 as indicated by

arrows A, with tip 34 of the handpiece in contact with skin 48.

When the handpiece is initially applied to the skin, the output of detectors 72 and 74 (FIG. 3) is stored by the control electronics of console 38 to form a baseline reading. This baseline reading will vary depending on the skin reflectivity at the illuminating wavelength and will be lower for darker skin types. The detection of lines on the skin is based on a drop in detector output below a predetermined fixed percentage of this baseline reading. As handpiece 32 is moved over skin 48 the position sensor of the detectors and control electronics detect the crossing of a line 46 and firing of the laser is triggered.

When apparatus 30 is in the automatic firing mode, depressing trigger 36 on handpiece 32 acts to enable automatic firing of the laser. The laser will not fire, regardless of detected line crossings, unless trigger 36 is also depressed.

After reaching an extreme one of lines 46, handpiece 32 is moved laterally by the width of the area treatable in the single laser firing, and handpiece 32 is again moved in the direction indicated by arrows A. The foregoing sequence is repeated until the desired area is treated. Movements of handpiece 32 in the direction indicated by arrows A may be all made in the same direction, or alternating between forward and reverse directions.

Referring next to FIG. 3, FIG. 4 and FIG. 5, further details of handpiece 32 and, in particular, of the position sensor therein (designated by numeral 41 in FIG. 3), are described. As noted above, handpiece 32 includes a diode-laser array. In a preferred example, a diode-laser array 50 includes a total of ten diode-laser-bar stacks 52 arranged

into rows of five. Each diode-laser-bar stack has a total of nineteen individual edge-emitting diode-lasers. The diode-lasers emit light at a wavelength between about 790 and 830 nanometers (nm). Diode-laser array 50 is assembled on a water-cooled backing-plate 53. Water is supplied to backing-plate 53 from control console 38, via a conduit 57 extending through umbilical sheath 40. Arranged in this way, diode-laser array 50 can deliver up to 1600 Watts (W) of laser-radiation.

Laser-radiation 54 from diode-laser array 50 is converged in the fast axis of the diode-laser bars by cylindrical microlenses (not shown) associated with stacks diode-laser-bar stacks 52, and converged in the slow axis of the diode-laser bars by a Fresnel lens 55. The laser radiation is then guided by a tapered light-guide 56 toward a lens 58, preferably of sapphire, in tip 34 of handpiece 32. Lens 58 most preferably has a square aperture to facilitate "tiling" together of sub-areas treated by single firings of the laser as described above with reference to FIG. 2.

Lens 58 has a contact surface 59 and is cooled by a cooling-fluid, preferably a mixture of water and ethylene glycol, chilled by a thermo-electric cooler (TEC) 60 (see FIG. 3). The cooling-fluid is circulated through a copper microchannel-cooling jacket 62 (see FIG. 5) in thermal contact with lens 58. Circulation of the cooling-fluid is effected by a pump 64 via delivery and return conduits 66 and 68 respectively (see FIG. 3).

Sensor 41 includes a light-source 70 (see FIG. 3), preferably a semiconductor light-source, such as a light-emitting diode (LED) or the like, and two photodetectors 72 and 74, such as photodiodes. These photodetectors are connected via electrical

connections (not shown) through umbilical sheath 40 to control electronics in console 38.

Light from light-source 70 is guided by an optical fiber 76 to tip 34 of handpiece 32 (see
5 FIGS. 3, 4 and 5). Light exiting optical fiber 76 incident on skin 48 is scattered through upper layers of the skin. A portion of the scattered light enters optical fibers 78 and 80 on opposite sides of optical fiber 76. The end faces of optical fibers 76, 78,
10 and 80 can be considered as apertures of the position sensor 41 of handpiece 32. Preferably these end faces are equally spaced in a straight line as shown in FIG. 4. Optical fibers 76, 78, and 80 can be considered as having proximal ends thereof adjacent
15 light-source 70 and detectors 72 and 74 respectively, and distal ends thereof in tip 34.

It is also most preferable that the optical-fibers are arranged at an angle to each other in tip 34 of handpiece 32. The angle converges towards
20 the distal ends of the fibers. The angle is selected to minimize the possibility of light from optical fiber 76 entering optical fibers 78 or 80 by specular reflection from any surface. One arrangement found to be optically effective and mechanically convenient
25 is that the fibers 78, 76 and 80 have a diameter between about 0.5 and 1.5 millimeters (mm) and are set the angles, in order 0 degrees, 15 degrees, and 30 degrees from the vertical (perpendicular to skin 48). The distal ends of the fibers are
30 preferably as close to each other as is consistent with securely retaining them in the sensor head. One reason for this is discussed further hereinbelow.

It is important that lines 46 are drawn with a medium (ink, paint or the like) which is transparent
35 to laser-radiation 54 from diode-laser array 50, but absorbent for light from light-source 70. Light from

light-source 70 must also be able to penetrate skin 48. By way of example, it has been found that for laser-radiation having a wavelength between about 790 and 830 nm, and a light-source 70 in a form of an LED emitting at a wavelength of about 660 nm, an ink containing the dye "Basic Blue 1" (CAS number 3251-06-0) is effective as a medium for lines 46.

Continuing now with particular reference to FIGS. 2 and 5, when end faces of optical fibers 76, 78 and 80 in tip 34 of handpiece 32 are all in contact with skin 48 in a region thereof between lines 46 (or outside grid 44 altogether) both optical fibers 78 and 80 will receive scattered light from optical fiber 76. The light so received will be transmitted to detectors 72 and 74. Control electronics connected to the detectors will record what may be described as a bright condition of the detectors.

As handpiece 32 is moved in the direction indicated by arrows A, either optical fiber 78 or optical fiber 80 will pass over a line 46 depending on the direction of movement (forward or reverse) of handpiece 32. If the width of lines 46 is equal to or greater than the diameter of the optical fibers, the optical fiber instantly over the line 46, and the detector associated therewith, will receive less scattered light because of the absorption of the line-marking medium. In this case, the control electronics will record a dark condition for that detector. Providing two detectors and associated optical fibers, arranged as shown and discussed provides the control electronics with a means of determining the direction of travel of handpiece as discussed below.

The control electronics are preferably programmed to record a "line-crossing" only after

both detectors 74 and 76 have registered a dark condition, in sequence. The sequence in which the dark conditions occur determines the direction of travel. The recorded line-crossing is used by the control electronics to trigger a firing of the laser for treatment. The number of line-crossings recorded can be used to establish a position of tip 34 of handpiece with respect to a starting (datum) point or line.

Another advantage of providing the above-discussed two detectors and fibers is in providing a means for determining whether or not tip 34 of handpiece 32 is in contact with skin 48. If tip 43 loses contact with skin 48, detectors 72 and 74 will simultaneously register a dark condition. Control electronics can be programmed to use such a recorded simultaneous dark condition to prevent firing of the laser either automatically or manually, thereby preventing, for example, firing the laser in an attitude where it may be therapeutically ineffective.

The time interval between line-crossings can be used to determine the speed of travel of tip 34 of handpiece 32 over skin 48. One reason for requiring knowledge of the speed of travel is to prevent handpiece 32 from being moved so quickly that, at the maximum practical firing rate of diode-laser array 52, (the laser) sequentially treated sub-areas of skin 48 can not be contiguous. By way of example, in above-described apparatus 30, the maximum firing rate is between about four and eight Hertz (Hz). Another reason is that too rapid a motion can reduce the effectiveness of chilled lens 58 in cooling skin to be treated.

To optimally prevent such occurrences, it is desirable to know the speed of travel of the handpiece before it has moved completely out of a

last-treated sub-area of skin 48, and preferably also before the laser is first fired. This can be achieved by spacing lines 46 at some sub-multiple of the width (or length) of a treated sub-area, for example at one-half or one-third that width. Correspondingly, respectively two or three sequential line-crossings will need to be recorded by the control electronics of console 38 in order to trigger a laser firing, while consecutive recorded sequential line-crossings are used to determine the speed of travel of handpiece 32.

From the speed of travel determination, it is possible to provide a simple audible or visual warning of excess speed of travel and even to prevent firing of the laser if a predetermined speed threshold is exceeded. Referring again to FIG. 2, a simple visual display may take the form of three different colored LEDs 82, 84, and 86, located on the back of handpiece 32, these diodes being activated, for example, according to whether the rate of travel is respectively slower than optimal, optimal, or faster than optimal. Those skilled in the art may devise other speed display forms without departing from the spirit and scope of the present invention such as an (apparently) moving bar type or "thermometer" type display of the type often used for sound level indication in electronic sound recording apparatus.

Reasons for preventing a laser firing, be they related to speed of travel or lack of contact, and the position at which firing was prevented can be displayed on display 43 of console 38. This provides that an operator can correct the reasons for prevention of firing and resume automatic firing at the point of termination, or treat individual

untreated sub-areas, one by one, by manually firing the laser.

It is pointed out here that instead of lines drawn in a medium which is darker than the skin as discussed above, it is also possible to employ an medium (ink) containing a fluorescent agent such as fluorescein (resorcinolphthalein, $C_{20}H_{12}O_5$). When excited by light, for instance from a light-source (LED) 70, having a wavelength centered near 494 nm, fluorescein emits light centered at 520 nm. A detector with a matched filter, for example an interference filter having a passband full width at half maximum transmission (FWHM) of 10 nm, at a peak transmission wavelength of 520 nm, can selectively detect this fluorescent emission. Here, since light emission is being detected rather than light absorption, line crossings can be detected equally effectively on skin of any natural color.

It should be noted, here, that in this specification, it is contemplated, unless otherwise stated, that any computation or signal evaluation required for position determination, laser firing decisions and the like is accomplished by one or more electronic processors in control circuitry of console 38. Communication for this purpose with devices incorporated in handpiece 32 and any below described variations thereof is accomplished via umbilical sheath 40 as exemplified above. Any remote displays or sensor devices are assumed to be connected directly to control electronics of console 138. It is emphasized, here, that this assumption is made at least for convenience of description and should not be considered limiting. Those skilled in the art will recognize that processing devices could be located remote from console 38, proximate devices which electronic

control is required, for example, in a handpiece 32, or in a computer such as a personal computer (PC). Should such remote processing devices be used, the manner of interconnection of the processing devices will be evident to those skilled in the art from the functional descriptions of embodiments presented herein.

Continuing now with a description of other preferred embodiments of the present invention, a preferred apparatus and method of the present invention is described above in terms of automatic firing by detecting crossings of lines in a parallel grid of lines drawn on skin to be treated with manual lateral shifting of handpiece 32 between linear automatic firing sequences. In another preferred method and apparatus in accordance with the present invention, automatic firing is provided for both longitudinal and lateral movement of handpiece 32. A brief description of this method and apparatus is set forth below with reference to FIG. 6 and FIG. 7

Referring first to FIG. 6, a grid 44X is drawn on skin 48 being treated using a medium of the types discussed above. Grid 44X comprises above-discussed equally-spaced parallel lines 46 and, additionally, another set of equally-spaced parallel lines 46X orthogonal to lines 46. Lines 46 and 46X are preferably spaced apart by a distance equal to respectively the length and width of the area treatable in a single firing of the laser or a sub-multiple of that dimension. If the area treatable in a single laser firing is made square, of course, the spacing of lines 46 and 46X is equal. Longitudinal and lateral motion is designated in FIG. 6 by arrows A and B respectively.

Referring now to FIG. 7, a handpiece 32X for practicing the method of FIG. 6 includes at least one

additional sensor (not shown), similar to above-described sensor 41 but arranged to detect lateral line-crossings. In such a lateral line-crossing sensor, apertures of the sensor would be aligned
5 orthogonal to those of above described sensor 41. This is illustrated in FIG. 7 by apertures (optical fiber ends) 78X, 76X, 80X. Preferably, there are two (a pair of) sensors for each direction as illustrated in FIG. 7 by the additional sensor apertures.
10 Apertures for each pair of sensors are parallel to each other and spaced apart, preferably by at least a width of a line 46 or 46X. This arrangement avoids problems that would be created by having only one set of sensors for a particular direction of travel
15 aligned over a line in the direction intended for the sensor of the opposite direction.

From the above discussion, those skilled in the art will be able to devise electronic processing logic for interpreting information from such a set of
20 sensors without further explanation. One such processing method, for example may include, displaying each therapeutically-effective, automatic firing of the laser as a square on display 43 of console 38, the position of the square corresponding
25 to its position in grid 44X of FIG. 6. This would provide an instant visual indication of the existence and position of any spots which had not been effectively treated.

Referring now to FIGS. 8-11, in still another
30 method of operating apparatus 30, a ruled strip 90 is placed, with equally-spaced rulings 92 thereof uppermost, on skin 48 to be treated (see FIG. 8). Rulings 92 are preferably spaced apart by a distance equal to a linear dimension of the area treatable in
35 a single firing of the laser or a sub-multiple of that dimension, for reasons discussed above with

reference to handpiece 32 of FIG. 2. Rulings 92 may also be arbitrarily spaced by some distance relatively small by comparison with the linear dimension of the area treatable in a single pulse, for example as small as the width of a ruling. This allows detection of many indicia crossings which can enable calculation of increasing or decreasing speed of movement of the handpiece.

5 A handpiece 32Y, with lens 58 thereof in contact with skin 38, is maintained in contact with strip 90 (see FIG. 11) and moved in a direction indicated by arrows A (see FIG. 8). Tip 34Y of handpiece 32 has its width reduced at its contact end to form steps 94 on each side thereof. Steps 94 preferably have a height just sufficient to allow horizontal surfaces 96 thereof to make contact with strip 90 when tip 34Y is in contact with skin 48 (see FIG. 11).

10 Handpiece 32Y includes at least one position sensor 41 (light-source and detectors thereof not shown in FIGS. 8-11) including an optical fiber 76 delivering light from the sensor's light-source and optical fibers 78 and 80 for transmitting light to the sensor's detectors. The optical fibers are threaded through handpiece 32Y and are held by a contact block 98 in the above-described alignment and angular relationship of sensor 41 of handpiece 32. Contact block 98 is attached to an extended portion 35 of handpiece 32Y. Extended portion 35 has a width equal to the width of tip 34Y across steps 94. Ends of optical fibers 76, 78 and 80 are held flush with base 102 of block 100 which is flush with horizontal surface 96 of step 94.

25 Strip 90 is preferably made from a translucent (bulk scattering) material, for example, a fluorocarbon polymer. Rulings 92 are made opaque to

light from the light-source of sensor 41. It is also possible to use lines or rulings drawn on any diffuse reflector, for example, dark lines drawn on white (bright) paper or white, (bright) diffusely-reflective lines drawn on a black (dark) surface, i.e., a surface which absorbs light at the wavelength emitted by light-source 70. There is no requirement that the rulings be transparent to light from diode-laser array 50. Crossings of rulings 92 of strip 90 are detected and electronically processed in the manner described above with reference to the apparatus and method of FIG. 2. A crossing can be detected as a reduction in light detected by a detector 72 or 74, for example, in the case of dark lines on a bright background, or as an increase in the detected light, for example in the case of bright lines on a dark background.

Typically, the method of FIG. 8 is practiced by an operator holding strip 90 in position on skin 48 with one hand and moving handpiece 32Y with the other hand. As depicted in FIGS. 9-11, two position sensors 41 may be provided, with apertures of one sensor on one side of tip 34Y and apertures of the other sensor on the other side of tip 34Y. Selective activation of one or the other of the sensors provides for right or left hand operation of handpiece 32Y.

It should be noted here, that while position sensors 41 are described above with reference to a remote light-source and detectors optically communicating with sensor apertures by means of optical fibers, this should not be considered as a limiting configuration for such sensors. By way of example, in a handpiece similar to handpiece 32Y, a position sensor, logically functioning as described above, may be incorporated in a block of similar size

and similarly position to block 100, with the light-source and detectors of the sensor incorporated in a single semiconductor chip.

5 The method of FIG. 8, using a separate guide strip rather than lines drawn on skin 48, permits that a position sensor may function by means other than optical. By way of example, a guide strip may be provided with magnetized rulings or indicia. This may be in the form of a preferentially magnetized
10 strip of a form similar to that on credit cards and the like, or rulings in a magnetic medium on a strip of a non-magnetic material. One preferred sensor for such indicia would include at least one and preferably two (for direction sensing) magnetic pickup heads
15 located in a block of similar size and position to block 100. The two pickup heads would provide for a direction-sensing capability as described above for sensor 41. In another example, rulings or indicia 92 may be in the form of depressions in (or protrusions
20 above) the upper surface of guide strip 90 with the indicia being sensed by two styli located in a block of similar size and position to block 100.

One advantage of the method of FIG. 8, whether optical, magnetic or mechanical indicia are used, is
25 that higher sensing resolution is possible compared with the sensing resolution obtainable in the method of FIG. 2. The higher resolution permits a closer spacing of indicia, which is of particular advantage in sensing the speed of movement of the handpiece,
30 and even allows a determination of whether the speed of movement is increasing or decreasing.

Regarding speed of movement of the handpiece, as discussed above, there are two primary criteria which may determine a maximum possible speed of
35 movement for the handpiece. One of these criteria is the maximum possible firing rate of the laser, the

other is the rate at which chilled lens 58 can adequately cool skin 48. Should the latter be the limiting criterion, the limitation can be overcome by pre-cooling an untreated sub-area of skin 48 while an adjacent sub-area of the skin is being treated. Referring to FIGS. 9-11, one preferred means of effecting such a pre-cooling is to provide a pre-cooling plate 104 of about the same area as, and adjacent to, lens 58 and about level with contact surface 59 thereof.

Pre-cooling plate 104 is preferably formed from a material having a high coefficient of thermal conductivity such as copper. If copper is selected, it is preferable that it be coated or plated with a hard corrosion-resistant material, for example, nickel or rhodium. In handpiece 32Y, pre-cooling plate 104 is completely cooled by attaching it in thermal contact with cooling jacket 62 (not visible in FIGS. 9-11). Those skilled in the art may devise other arrangements for cooling pre-cooling plate 104 without departing from the spirit and scope of the present invention. Provision of the pre-cooling plate reduces the amount of cooling which must be provided by chilled lens 58, and can thus permit a speed of movement up to the laser firing rate limit for apparatus 30.

Referring now to FIG. 12 and FIG. 13, still another automatic firing apparatus and method in accordance with the present invention includes placing a ruled guide strip 91, on edge, in contact with skin to be treated, and sensing crossings of rulings 92 thereon using a side-looking position sensor incorporated in a handpiece 32W in accordance with the present invention. The side-looking position sensor is similar to above-described sensor 41 with the exception that transmitting

aperture 76 and receiving apertures 78 and 80 thereof face in a direction parallel to the plane of skin being treated. Apertures 76, 78 and 80 are located in block 110 attached to a lateral extension 112 of handpiece 32W.

In one preferred example of operation of handpiece 32, guide strip 91 is made from translucent material having opaque rulings 92, and handpiece 32W is moved, with sensor block 110 thereof in contact with guide-strip 91. Line-crossing detection occurs in the manner described above with respect to sensor 41 of handpiece 32. Alternatively, the guide-strip could be made of a reflecting material such as a metal and having a plurality of slots machined therein to define the rulings. In this case, a drop in detected light intensity would correspond to a line crossing.

Two position sensors with apertures thereof on opposite sides of handpiece 32W may be individually, selectively activated to provide for right or left hand operation of the handpiece as discussed above with reference to handpiece 32Y. Sensing methods are not limited to optical methods as described but may include magnetic and mechanical methods as discussed above.

A particular advantage of the guide strip arrangement of handpiece configuration of FIGS. 12 and 13 is that relative vertical motion (perpendicular to skin 48) between the handpiece and the guide strip is possible while still maintaining sensor apertures 76, 78 and 80 in contact with the ruled surface of the guide strip. This is particularly advantageous when treating skin of a strongly contoured body member such as a knee. Adding an additional sensor 41R on one or both sides of handpiece 32W (see FIG. 12) provides that rotary

motion of the handpiece, in a direction indicated by arrows E, can be detected. This can provide an operator with a warning should the handpiece be inadvertently inclined in direction E to a degree which would compromise proper therapeutic treatment.

Referring now to FIG. 14, FIG. 15, FIGS. 15A-D and FIG. 16, another handpiece 32R in accordance with the present invention is configured for automatic firing without the need for a separate guide-strip or markings ruled on skin to be treated. Handpiece 32R includes a wheel or roller 120 which rotates about an axle 122 extending from tip 34R of the handpiece (see FIG. 16).

Roller 120 is arranged to make contact with skin 48 being treated when lens 58 of the handpiece makes contact with the skin. Moving the handpiece in the (longitudinal) direction indicated by arrows A causes roller 120 to rotate. Roller 120 includes radial markings or indicia 124 on the side thereof facing handpiece 32R. Indicia 124 have equal angular spacing. Handpiece 32R includes a position sensor 41 having side-looking apertures 76, 78 and 80 positioned to detect motion of indicia 124 in the manner described above in which similar sensors detect motion of a handpiece over fixed indicia.

The angular spacing of indicia 124 may be selected such that peripheral spacing of the indicia on roller 120 is equal to, or some sub-multiple of, the length of lens 58. Sensor 41 can thereby provide signals for automatic firing and speed of movement calculation as described above. Alternatively, the spacing may be reduced to the point where the line spacing is relatively small compared with the length of the lens, for example, about equal to a line width or less such that. In this case, with revolution of roller 120, sensor 41 generates a stream of signals

similar to those generated by a conventional shaft encoder. This would allow automatic firing to be effected at any predetermined interval simply by correspondingly programming control electronics of console 38.

Preferably, rotary motion of roller 120 is damped such that the roller can not continue to rotate if contact thereof with skin 48 is lost. This provides that signals from sensor 41 can be used to determine loss of contact of handpiece 32R with skin 48. As an alternative or backup, however, another sensor 41C (see FIGS. 15, FIG. 15A, FIG. 15B, 15C and 16) can be provided, the purpose of which is only to sense contact, or loss thereof, with skin 48.

Contact sensor 41C is similar to above described position sensor 41 except for the arrangement of light delivery optical fiber 76 and light receiving fibers 78 and 80 in a block 100C (see FIGS. 15A-B for details) for holding the ends of the optical fibers in alignment with each other. In block 100C the relative angle between the fibers is about the same as for those of above-described sensor 41 but with the angular subtense diverging at the distal ends of the fibers rather than converging. This is achieved by crossing the receiving fibers 78 and 80 in block 100C and arranging transmitting fiber 76 to bisect the angle between the receiving fibers.

A result of this arrangement is that the amount of scattered light received by the receiving fibers is somewhat reduced compared with the arrangement of sensor 41. The possibility of receiving fibers 78 and 80 receiving light from optical fiber 76 by any optical mechanism other than volume scatter through skin 48 is essentially eliminated. Because of this,

the effectiveness of sensor 41C as a skin-contact sensor is increased compared with that of sensor 41.

Referring to FIG. 15C, where this arrangement functions as a skin-contact sensor only, it is possible to use a sensor block 100D which includes only a sending fiber 76 and a receiving fiber 78. This allows a greater angular divergence between the sending and receiving fibers. In FIG. 15D is schematically depicted the output of a detector cooperative with a sensor head 100D when the sensor head (the distal tips of fibers 76 and 78) is at distances of between 0.0 and 3.0 mm for surfaces of opaque grey plastic (curve F) light-colored skin (curve G) and translucent white plastic (curve H). About 0.5 milliwatts (mW) of light at a wavelength of about 660 nm is delivered from optical fiber 76. Optical fibers 76 and 78 each have a diameter of 1.0 mm and are inclined at 40° from vertical, i.e., with an angle of 80° therebetween. The tips of the optical fibers are laterally and longitudinally separated by 2.0 mm. It can be seen that there is essentially zero detector output from the opaque grey plastic surface at any distance up to contact. A similar result was obtained on a rough (diffusely reflecting) steel surface.

For skin (skin of a finger in this experiment) and translucent plastic, output increases gradually as the sensor approaches the surfaces. Applying a force of 10.0 grams (g) to the sensor head on the skin surface caused the detector output to rise sharply from about 18.0 to 29.5, indicating the effectiveness of the sensor head as a contact sensor. A further increase in force provided no significant increase in output. In practice, a threshold level of detection can be set at the detector output level at skin contact. It is a relatively simple matter to

provide a calibration capability, via a potentiometer or the like, to adjust the threshold for different skin shades. Contact of the sensor head, or lack thereof, can then be determined according to whether the detector output is above or below the set threshold level.

Referring now to FIG. 17 and FIG. 18, another handpiece 32E in accordance with the present invention includes a wheel or roller 130. Roller 130 is rotatable on an axle 132 which extends through a bearing housing 134 into an extended portion 37 of tip 34E of handpiece 32E. Axle 132 engages a shaft encoder 136 located in extended portion 37 of tip 34E.

Roller 130 is arranged to make contact with skin 48 being treated when lens 58 of the handpiece makes contact with the skin. Moving the handpiece in the (longitudinal) direction indicated by arrows A causes roller 130 to rotate. Rotation of roller 130 is monitored by shaft encoder 136. Signals from shaft encoder 136 representative of the angular position or degree of rotation of roller 130 are transmitted to control electronics in control console 38 (see FIG. 1) and used for triggering automatic firing and computing speed of motion of the roller. Making or breaking contact with skin 48 by tip 34E of handpiece 32E can be detected by the control electronics detecting respectively initiation and termination of rotation of roller 130 via signals from shaft encoder 136. Alternatively or additionally, an optical skin contact sensor of the type described above with reference to handpiece 32R may be provided.

Referring now to FIG. 19, FIG. 20 and FIG. 21, another handpiece 32H in accordance with the present invention is illustrated. Handpiece 32H includes a

detachable housing 121 (shown in phantom in FIG. 21) which attaches to tip 34 of the handpiece.

Detachable housing 121 includes a wheel or roller 123 arranged to engage skin 48 being treated when lens 58 of tip 34 is placed in contact with the skin.

Roller 123 includes a series of equally-spaced, parallel (paraxial) longitudinal rulings 125 around a cylindrical surface of the roller (see FIG. 20). The spacing of the rulings is preferably equal to or some sub-multiple of the length of lens 58 for reasons discussed-above, for example, with reference to handpiece 32R. Alternatively the lines may be set sufficiently close together that the roller and detector function in the manner of a conventional shaft encoder as discussed above.

A sensor block 127 including distal ends of optical fibers 76, 78 and 80 of a position sensor 41 is located on tip 34 of handpiece 32H (see FIG. 21). Here, the distal ends of the fibers are arranged in a vertically-oriented line such that the position sensor can detect the passage of rulings 125 of roller 123 as the roller rotates responsive to motion of the handpiece over skin 48. From the detection of rulings, the position of handpiece 32H on skin 48 can be determined as discussed above.

Referring to FIG. 20A, an alternative roller 123A for handpiece 32H is illustrated. Roller 123A comprises two coaxial cylindrical portions 129 and bounding a cylindrical portion 131 coaxial therewith but having a lesser diameter than cylindrical portions 129. Here, paraxial rulings 125 are made on cylindrical portion 131. This helps minimize contact with the rulings on contacting skin 48 when roller 123A contacts skin 48 via cylindrical portions 129 thereof. Contact of rulings 125 with skin 48 could progressively lead to

contamination with skin grease, skin debris and the like. Such contamination could lead to errors in the accuracy of position determination by position sensor 41.

5 Sensor handpiece 32H is described above as including a position sensor 41 having a light-source and detectors thereof located in the body of the handpiece and connected to a sensor block by optical fibers. Those skilled in the art will recognize
10 however that a similarly functioning sensor head could be positioned in detachable housing 121 without departing from the spirit and scope of the present invention. In fact it is possible to locate all components of a position detector in detachable
15 housing 121, requiring only an electrical connection with the body of the handpiece for power and data communication.

 It is pointed out here that indicia on any above-described rollers may be dark lines on a bright
20 background or bright lines on a dark background. Alternatively, the indicia may be fluorescent, or may be magnetic if sensor 41 is replaced with a magnetic pick-up arrangement.

 Referring now to FIG. 22, another handpiece 32T in accordance with the present invention includes a
25 transponder 140 and a receiver 142. Preferably, transponder 140 is an ultrasonic emitter and receiver 142 is an ultrasonic detector. Transponder 140 sends a signal-pulse (dashed
30 line 144) to a screen or wall 146 located proximate a patient 148 on whose back skin 48 is being treated. Here, screen 146 is shown mounted on a table 150 on which patient 148 is lying in a face-down position.

 Receiver 142 receives an echo (a return-pulse)
35 of the signal-pulse sent by transponder 140 (dashed line 152) from screen 146. Control electronics of

console 38, connected to transducer 140 and receiver 142 record the time of sending signal-pulse 144 and time of receiving echo 152 corresponding thereto and determine a time difference between the sending and receiving. The time difference between the sending of signal-pulse 144 and the receiving of echo 152 provides a measure of the position of handpiece 32T with respect to screen 146 and, accordingly, with respect to patient 148 as the handpiece is moved in a longitudinal direction indicated by arrows A. These position measurements are used by control electronics of console 38 to automatically trigger firing of the laser at equal position increments of handpiece 32, and, optionally, to monitor the speed of motion of handpiece 32T as discussed above with reference to other embodiments of the apparatus and method of the present invention.

It should be noted here that the treatment illustrated in FIG. 22 and the position of screen 146 with respect to patient 148 are merely exemplary. Those skilled in the art may devise other screen locations adapted to other treatments without departing from the spirit and scope of the present invention.

It should also be noted that while an ultrasonic emitter and receivers are preferred in the above described embodiment of the present invention, the operating principles of this embodiment are applicable if transponder 140 (and corresponding receivers 142) rely on sending and detection of signals other than ultrasonic signals. By way of example, these may be optical signals (pulses) generated by a laser, forming in effect a laser rangefinder. The laser may be located in, or on, handpiece 32T, or may be remote therefrom with

radiation from the laser being delivered to transponder 140 by an optical fiber. The signals may also be radar signals (pulses) with transponder 140 being a miniature, (for example incorporated in a semiconductor chip) radar transmitter. In the case of optical or radar signals, electronic processing of the signals may prove to be more complex than for ultrasonic signals, because of the relatively short distances traversed by signal pulses and, correspondingly, the relatively very short time between sending and detection thereof.

Referring now to FIG. 23, another handpiece 32D in accordance with the present invention includes a transponder 160. Preferably, transponder 160 is an ultrasonic emitter. Transponder 160 sends a signal-pulse (dashed lines 162) radiating therefrom in a diverging manner to three receivers 164, preferably ultrasonic detectors incorporated in a video display unit (VDU) 166 having a display 168. Here, VDU 166 is shown positioned proximate table 150 on which patient 148, on whose back skin 48 is being treated, is lying in a face-down position.

In one example of signal processing for the arrangement of handpiece 32D and receivers associated therewith, for each signal-pulse the difference in arrival time at each the receivers is recorded. Based on this difference in arrival time, and on the spacing of the receivers, control electronics associated with the transponder and receivers determine, by triangulation, a position in longitudinal direction A and lateral direction B for transponder 160 relative to a plane in which the receivers are located. Here the plane is of the front of VDU 166. This position measurement is used by control electronics of console 38 to automatically trigger firing of the laser depending on its lateral

and longitudinal position. A visual record of the firings is presented on display 168.

It should be noted here that, in theory at least, only two detectors are necessary to provide two dimensional position location for the handpiece. Providing three detectors can increase the accuracy of two dimensional position location and also provide information on position in a third (perpendicular to the general plane of the skin) direction. This information can be useful if a contoured area of skin, for example, a knee, is being treated.

In one example of operation of handpiece 32D, point 170P on patient 148 designates the lower left-hand corner (origin) of an area of skin 48 to be treated. This area is considered to be divided into a series on sub-areas equal in dimension to lens 58 of handpiece 32D. Point 170D on display 168 is electronically arranged to represent point 170P on patient 48.

The instantaneous position of handpiece 32D relative to point 170P is indicated on display 168 by a square "cursor" 169 having dimensions representing the area treatable in a single firing of the laser. Treatment is initiated by placing tip 34 of handpiece 32D in contact with skin 48 of patient 148 and activating trigger 36 of the handpiece to begin automatic firing.

Each successful firing is recorded on display 169 as a solid square, thereby providing a direct indication of progress of then treatment and of any areas such as an area 171 which may have been "missed". Control electronics may also be arranged to store an electronic map of successful firings. The stored electronic map can be used by the control electronics to automatically fire the laser when the position detection system senses that the handpiece

tip is contacting the skin in a missed area. The stored electronic map can be also be used by the control electronics to prevent manual firing of the laser if the handpiece tip is in contact with the skin in an area that has already been successfully treated.

It should be noted here that receivers 164 are shown integrated into VDU 166 as one convenient location for the detectors. Receivers 164 may also be located remote from VDU 166 and supported on a separate frame and locations may be varied according a specific treatment. Such locations may be selected and varied without departing from the spirit and scope of the present invention.

While preferred embodiments of the present invention are described above with reference tracking motion of a handpiece in which a laser source is located, the present invention is not limited to use with such a handpiece. Principles of the application are also applicable to a handpiece which delivers radiation received from a remotely located source of laser-radiation. Such a handpiece, for example, may receive radiation from the remote source via an optical fiber or bundle of optical fibers or via a hollow articulated arm. Further, principles of the present invention are equally applicable if treatment does not require that the tip or delivery aperture of the handpiece is in contact with skin being treated. By way of example, the tip may include a lens for shaping or focussing the delivered radiation and may be spaced at a relatively short distance (about one or two centimeters) from the skin with spacing being maintained by an open jig in contact with the skin.

It should also be noted that automatic firing in accordance with the present invention has been described with reference to controlling firing such

that sub-areas treated in a single filing are "tiled" together more or less contiguously to cover a total area to be treated, any of the above described embodiments to covering an area by overlapping
5 treated sub-areas in a predetermined pattern. By way of example, each treated (in a single firing) sub-area may overlap the previously treated sub-area by half the length of the sub-area. This may be done for example to avoid the possibility of any narrow
10 untreated areas being left between treated sub-areas.

Generally, the present invention is described and depicted herein in terms of a preferred and other embodiments. The invention, however, is not limited by those embodiments described and depicted. Rather,
15 the invention is limited only by the claims appended hereto.

WHAT IS CLAIMED IS:

1. A method of treating an area of skin with a laser by delivering a series of laser-radiation pulses to the skin, each of the laser pulses treating a sub-area of the area to be treated, the method comprising the steps of:

(a) providing a laser which, on being fired, generates a pulse of laser-radiation;

(b) providing a handpiece for delivering a pulse of laser-radiation from said laser to the skin being treated;

(c) while moving the handpiece over the skin being treated, electronically determining the location of said handpiece in the area of skin being treated; and

(d) automatically firing the laser when said electronically determined location corresponds to a sub-area to be treated.

2. The method of claim 1 wherein said location determining step (c) comprises the steps of (i) providing a plurality of regularly spaced indicia on or adjacent the area of skin being treated (ii) providing at least one sensor on the handpiece said sensor arranged to detect passage of the handpiece by one or more of said indicia as the handpiece is moved over the skin being treated and wherein in step (d) said automatic firing is triggered by the passage of the handpiece by one or more of said indicia.

3. The method of claim 2, wherein said indicia are one of graphic indicia, magnetic indicia, and mechanical indicia.

4. The method of claim 3 wherein said indicia are graphic indicia.

5. The method of claim 4, wherein said sensor includes a light-source arranged to direct light onto the skin being treated such that the thus directed light is scattered by the skin being treated; wherein
5 said sensor includes one or more light detectors arranged to detect said scattered light; wherein said graphic indicia are equally-spaced parallel lines drawn on the area of skin being treated in a medium which is at least partially opaque to the wavelength
10 of light emitted by said light-source and substantially transparent to the wavelength of said pulse of laser radiation; and wherein passage of the handpiece by any one of said indicia results in a reduction in said scattered light detected by said at
15 least one detector, said reduction in scattered light indicating that one of said indicia has been passed.

6. The method of claim 4, wherein said graphic indicia are equally-spaced parallel lines drawn on a strip of material placed on or adjacent to the area
20 of skin being treated; wherein said sensor includes a light-source arranged to direct light onto the strip such that the thus directed light is scattered by the strip; wherein said sensor includes one or more light detectors arranged to detect said
25 scattered light; wherein said strip is diffusely reflective at the wavelength of light emitted by said light-source for said directed light and said lines are drawn in a medium which is absorbent at the wavelength of light emitted by said light-source; and
30 wherein passage of the handpiece by any one of said indicia results in a reduction in said scattered light detected by said at least one detector, said reduction in scattered light indicating that one of said indicia has been passed.

7. The method of claim 4, wherein said graphic indicia are equally-spaced parallel lines drawn on a strip of material placed on or adjacent to the area of skin being treated; wherein said sensor includes
5 a light-source arranged to direct light onto the strip; wherein said strip is absorbent at the wavelength of light emitted by said light-source and said lines are drawn in a medium which is diffusely reflective at the wavelength of light emitted by said
10 light-source; wherein said sensor includes one or more light detectors arranged to detect directed light diffusely reflected by said lines; and wherein passage of the handpiece by any one of said indicia results in an increase in light detected by said at
15 least one detector, said increase in detected light indicating that one of said indicia has been passed.

8. The method of claim 4, wherein said graphic indicia are equally-spaced parallel lines drawn on a strip of material placed on or adjacent to the area
20 of skin being treated; wherein said sensor includes a light-source arranged to direct light onto the strip; wherein said lines are drawn in a medium which is fluorescent on irradiation with light emitted by said light-source; wherein said sensor includes one
25 or more light detectors arranged to said fluorescence; and wherein passage of the handpiece by any one of said indicia results in increase in light detected by said at least one detector, said increase in detected light indicating that one of said indicia
30 has been passed.

9. The method of claim 3 wherein said indicia are magnetic indicia

10. The method of claim 3 wherein said indicia are mechanical indicia.

11. The method of claim 2 wherein said indicia are spaced apart by a distance equal to one of a linear dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a linear dimension of the sub-area irradiated by said laser pulse; and a distance relatively small compared with a linear dimension of the sub-area irradiated by said laser pulse.

12. The method of claim 1 wherein said location determining step (c) comprises the steps of (i) providing a roller on the handpiece, said roller arranged to contact the skin being treated and rotate in response to the handpiece being moved over the skin being treated, and said roller having a plurality of regularly spaced indicia thereon (ii) providing at least one sensor on the handpiece said sensor arranged to detect passage by said sensor of one or more of said indicia as said roller rotates and wherein in step (d) said automatic firing is triggered by the passage by said sensor of one or more of said indicia.

13. The method of claim 12, wherein said indicia are radially extending lines on a side of said roller.

14. The method of claim 13, wherein said indicia are spaced apart at the periphery of said roller by a distance equal to one of a linear dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a linear dimension of the sub-area irradiated by said laser

pulse; and a distance relatively small compared with a linear dimension of the sub-area irradiated by said laser pulse.

5 15. The method of claim 12 wherein said indicia are longitudinally extending lines on a first cylindrical surface of said roller.

10 16. The method of claim 15, wherein said indicia are spaced apart at the periphery of said roller by a distance equal to one of a linear dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a linear dimension of the sub-area irradiated by said laser pulse; and a distance relatively small compared with
15 a linear dimension of the sub-area irradiated by said laser pulse.

 17. The method of claim 15 wherein said first cylindrical surface of said roller is a skin contacting surface of said roller.

20 18. The method of claim 15 wherein said roller has a second cylindrical surface for contacting the skin, and first cylindrical surface has a smaller diameter than the diameter of said second cylindrical surface.

25 19. The method of claim 1 wherein said location determining step (c) comprises the steps of (i) providing a roller on the handpiece, said roller arranged to contact the skin being treated and rotate in response to the handpiece being moved over the
30 skin being treated said roller being axially connected to a shaft encoder said shaft encoder

providing signals used for said electronic location determining.

20. The method of claim 1 wherein said location determining step (c) comprises the steps of (i)
5 providing a screen adjacent the skin being treated
(ii) providing a transponder on the handpiece, said transponder arranged to emit a regular train of signal-pulses toward said screen such that said signal-pulses are incident thereon and a return-pulse
10 corresponding to each of said incident signal-pulses returns to the handpiece (iii) providing a receiver on said handpiece for receiving said return pulses (iv) determining an elapsed time between emitting a said signal-pulse and receiving a said corresponding
15 return-pulse, said elapsed time being representative of said location of said handpiece.

21. The method of claim 20 wherein said signal-pulses are ultrasonic pulses.

22. The method of claim 20 wherein said signal-pulses are optical pulses.
20

23. The method of claim 20 wherein said signal-pulses are radar pulses.

24. The method of claim 1 wherein said location determining step (c) comprises the steps of (i)
25 providing a transponder on the handpiece, said transponder arranged to emit a regular train of signal-pulses each thereof in diverging beam (ii) providing at least two spaced-apart receivers located in a position remote from said handpiece, within the divergence of said beam, for receiving said signal
30 pulses (iii) based on the spacing of said receivers

and an arrival time of said signal pulses at said receivers determining said location of said handpiece in at least length and width dimensions of said area of skin to be treated.

5 25. The method of claim 24 wherein said signal-pulses are one of ultrasonic pulses, optical pulses, or radar pulses.

 26. The method of claim 25 wherein said signal pulses are ultrasonic pulses.

10 27. The method of claim 24, wherein said area of skin to be treated is contoured and said three spaced apart receivers are provided, and said location of said handpiece in said area of skin to be treated is determined in length width and height
15 dimensions.

 28. The method of claim 25 wherein said signal-pulses are one of ultrasonic pulses, optical pulses, or radar pulses.

20 29. A method of treating an area of skin with a laser by delivering a series of laser-radiation pulses to the skin, each of the laser pulses treating a sub-area of the area to be treated, the method comprising the steps of:

25 (a) providing a laser which, on being fired, generates a pulse of laser-radiation;

 (b) providing a handpiece for delivering a pulse of laser-radiation from said laser to the skin being treated;

30 (c) while moving the handpiece over the skin being treated, electronically determining a location of said handpiece in the area of skin being treated

said location determining including (i) providing a plurality of regularly spaced indicia on or adjacent the area of skin being treated, and (ii) providing at least one sensor on the handpiece said sensor
5 arranged to detect passage of the handpiece by one or more of said indicia as the handpiece is moved over the skin being treated; and

(d) automatically firing the laser on detection of passage of the handpiece by one or more of said
10 indicia.

30. The method of claim 29 wherein said indicia are spaced apart by a distance equal to one of a linear dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a
15 linear dimension of the sub-area irradiated by said laser pulse; and a distance relatively small compared with a linear dimension of the sub-area irradiated by said laser pulse.

31. The method of claim 30 wherein said indicia are provided by a grid of parallel lines drawn on the
20 area of skin to be treated.

32. The method of claim 30 wherein said indicia are provided by first and second grids of parallel lines drawn on the area of skin to be treated, said
25 second grid being arranged orthogonal to said first grid, and wherein said handpiece is provided with at least first and second sensors, said first and second sensors for detecting passage of said handpiece by lines in respectively said first and second grids.

33. The method of claim 30 wherein said indicia are provided by a parallel rulings on a strip of
30

material placed on or adjacent the area of skin to be treated.

34. A method of treating an area of skin with a laser by delivering a series of laser-radiation
5 pulses to the skin, each of the laser pulses treating a sub-area of the area to be treated, the method comprising the steps of:

(a) providing a laser which, on being fired, generates a pulse of laser-radiation;

10 (b) providing a handpiece for delivering a pulse of laser-radiation from said laser to the skin being treated;

(c) while moving the handpiece over the skin being treated, electronically determining a location
15 of said handpiece in the area of skin being treated said location determining including (i) providing a roller on the handpiece, said roller arranged to contact the skin being treated and rotate in response to the handpiece being moved over the skin being
20 treated, and said roller having a plurality of regularly spaced indicia thereon and (ii) providing at least one sensor on the handpiece, said sensor arranged to detect passage by said sensor of one or more of said indicia as said roller rotates; and

25 (d) automatically firing the laser on detection of passage by the sensor of one or more of said indicia.

35. The method of claim 34, wherein said indicia are radially-extending lines on a side of
30 said roller.

36. The method of claim 35, wherein said indicia are spaced apart at the periphery of said roller by a distance equal to one of a linear

dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a linear dimension of the sub-area irradiated by said laser pulse; and a distance relatively small compared with a linear dimension of the sub-area irradiated by said laser pulse.

37. The method of claim 36 wherein said indicia are longitudinally-extending lines on a first cylindrical surface of said roller.

38. The method of claim 37, wherein said indicia are spaced apart at the periphery of said roller by a distance equal to one of a linear dimension of the sub-area irradiated by said laser pulse; a distance equal to a sub-multiple of a linear dimension of the sub-area irradiated by said laser pulse; and a distance relatively small compared with a linear dimension of the sub-area irradiated by said laser pulse.

39. A method of treating an area of skin with a laser by delivering a series of laser-radiation pulses to the skin, each of the laser pulses treating a sub-area of the area to be treated, the method comprising the steps of:

- (a) providing a laser which, on being fired, generates a pulse of laser-radiation;
- (b) providing a handpiece for delivering a pulse of laser-radiation from said laser to the skin being treated;
- (c) while moving the handpiece over the skin being treated, electronically determining a location of said handpiece in the area of skin being treated said location determining including (i) providing a screen adjacent the skin being treated, (ii)

providing a transponder on the handpiece, said transponder arranged to emit a regular train of signal-pulses toward said screen such that said signal-pulses are incident thereon and a return-pulse corresponding to each of said incident signal-pulses returns to the handpiece, (iii) providing a receiver on said handpiece for receiving said return pulses, and (iv) determining an elapsed time between emitting a said signal-pulse and receiving a said corresponding return-pulse, said elapsed time being representative of said location of said handpiece; and

(d) automatically firing the laser when said electronically determined location corresponds to a sub-area to be treated.

40. A method of treating an area of skin with a laser by delivering a series of laser-radiation pulses to the skin, each of the laser pulses treating a sub-area of the area to be treated, the method comprising the steps of:

(a) providing a laser which, on being fired, generates a pulse of laser-radiation;

(b) providing a handpiece for delivering a pulse of laser-radiation from said laser to the skin being treated;

(c) while moving the handpiece over the skin being treated, electronically determining a location of said handpiece in the area of skin being treated said location determining including (i) providing a transponder on the handpiece, said transponder arranged to emit a regular train of signal-pulses each thereof in diverging beam, (ii) providing at least two spaced-apart receivers located in a position remote from said handpiece, within the divergence of said beam, for receiving said signal

pulses, and (iii) based on the spacing of said receivers and an arrival time of said signal pulses at said receivers determining said location of said handpiece in at least length and width dimensions of said area of skin to be treated; and

(d) automatically firing the laser when said electronically determined location corresponds to a sub-area to be treated.

41. The method of claim 40, wherein said area of skin to be treated is contoured and three spaced-apart receivers are provided, and said location of said handpiece in said area of skin to be treated is determined in length width and height dimensions.

42. A method of treating an area of skin with a laser by delivering a series of pulses of electromagnetic radiation to the skin, each of the electromagnetic radiation pulses treating a sub-area of the area to be treated, the method comprising the steps of:

(a) providing a source of electromagnetic radiation which, on being fired, generates a pulse of electromagnetic radiation;

(b) providing a handpiece for delivering a pulse of electromagnetic radiation from said source thereof to the skin being treated;

(c) while moving the handpiece over the skin being treated, electronically determining the location of said handpiece in the area of skin being treated; and

(d) automatically firing the source of electromagnetic radiation when said electronically determined location corresponds to a sub-area to be treated.

43. In an apparatus for skin treatment using electromagnetic radiation, the apparatus including a source of the electromagnetic radiation and a handpiece cooperative therewith for delivering the electromagnetic radiation to skin being treated, the electromagnetic radiation being delivered by the handpiece through a transparent applicator therein, the applicator being in contact with the skin being treated during treatment, a method of sensing that the applicator is in contact with the skin, the method comprising the steps of:

(a) providing a light-source having an exit-aperture thereof on the handpiece, said exit-aperture configured to be in contact with the skin being treated when the applicator is in contact with the skin being treated;

(b) delivering light from said light-source via said exit-aperture thereof such that, when the applicator is one of proximate the skin or in contact with the skin, light delivered from said exit-aperture is transported laterally through the skin via volume scattering of said light;

(c) providing a detector having a receiving-aperture on said handpiece proximate said light-source exit-aperture;

(d) monitoring the output of said detector; and

(e) interpreting said monitored detector-output as an indication that the applicator of said handpiece has made or lost contact with the skin being treated.

44. A laser system for treating tissue comprising:

a laser for generating laser light;

a delivery device including a manually movable handpiece for delivering the laser light to the tissue;

5 a sensor associated with the handpiece for monitoring the movement of the handpiece with respect to the tissue, said sensor generating output signals; and

10 a processor for controlling the triggering of the laser in response to the receipt of the output signals in a manner to facilitate uniform treatment of the tissue over a large area with the laser light.

45. A laser system as recited in claim 44 further including ruled indicia spatially associated with the tissue to be treated and wherein the sensor is mounted on the handpiece in a manner to detect said indicia as the handpiece is moved thereby.

46. A laser system as recited in claim 45 wherein said indicia are formed by one of:

20 a) markings directly on the tissue to be treated; and

b) markings on a rule located proximate the surface of the skin.

47. A laser system is recited in claim 46 wherein said indicia are graphic and said sensor detects the indicia optically.

48. A laser system as recited in claim 47 wherein said sensor includes a light source aimed at said indicia, said sensor further including a photodetector configured to monitor changes in light caused by the presence of the indicia.

49. A laser system as recited in claim 44
wherein said sensor includes a wheel rotatably
mounted to the handpiece, said wheel rotating in
response to the movement of the handpiece across the
tissue and wherein said sensor monitors the rotation
of the wheel.

50. A laser system as recited in claim 49
wherein the wheel includes ruled indicia which are
monitored by the sensor.

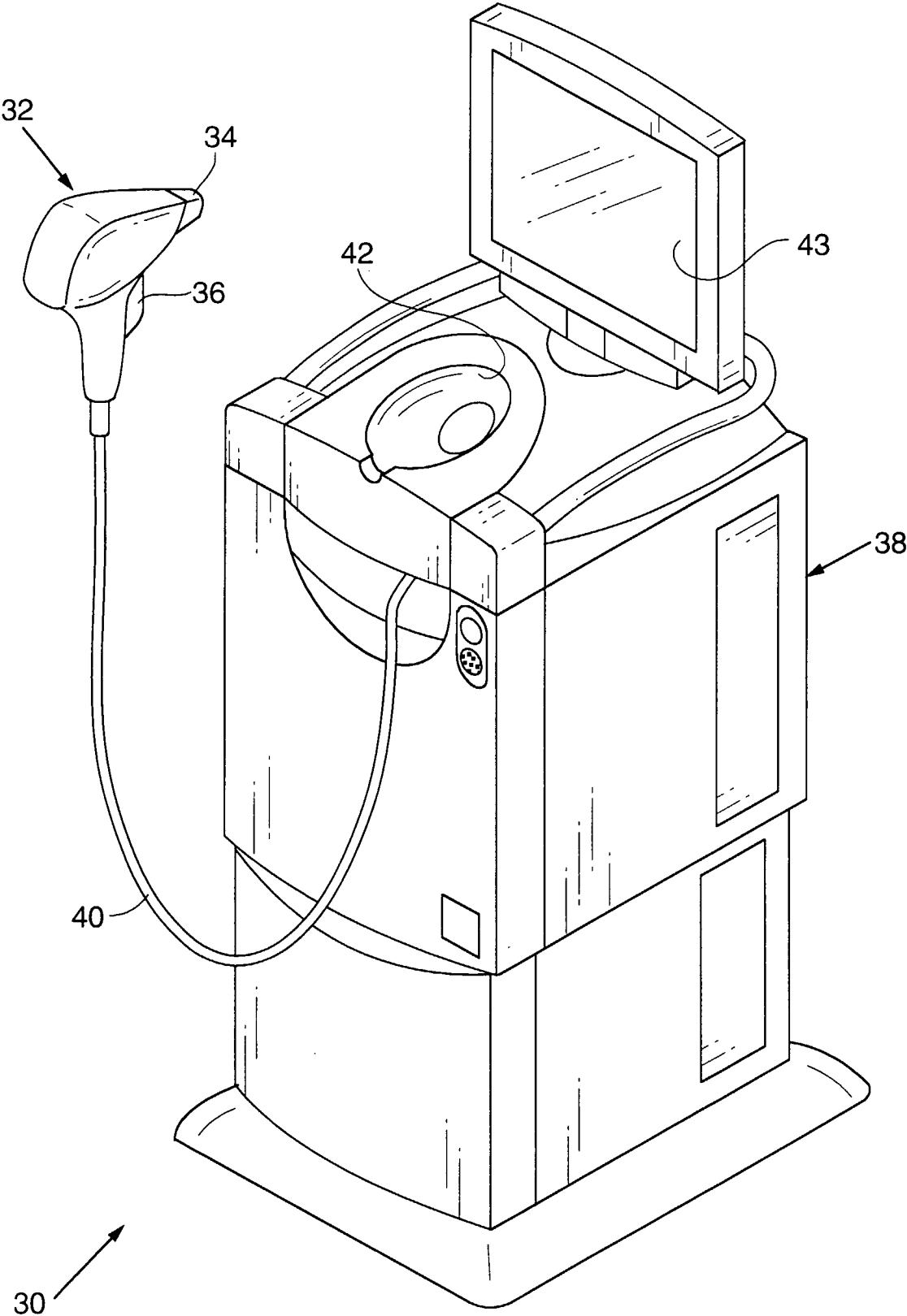


FIG. 1

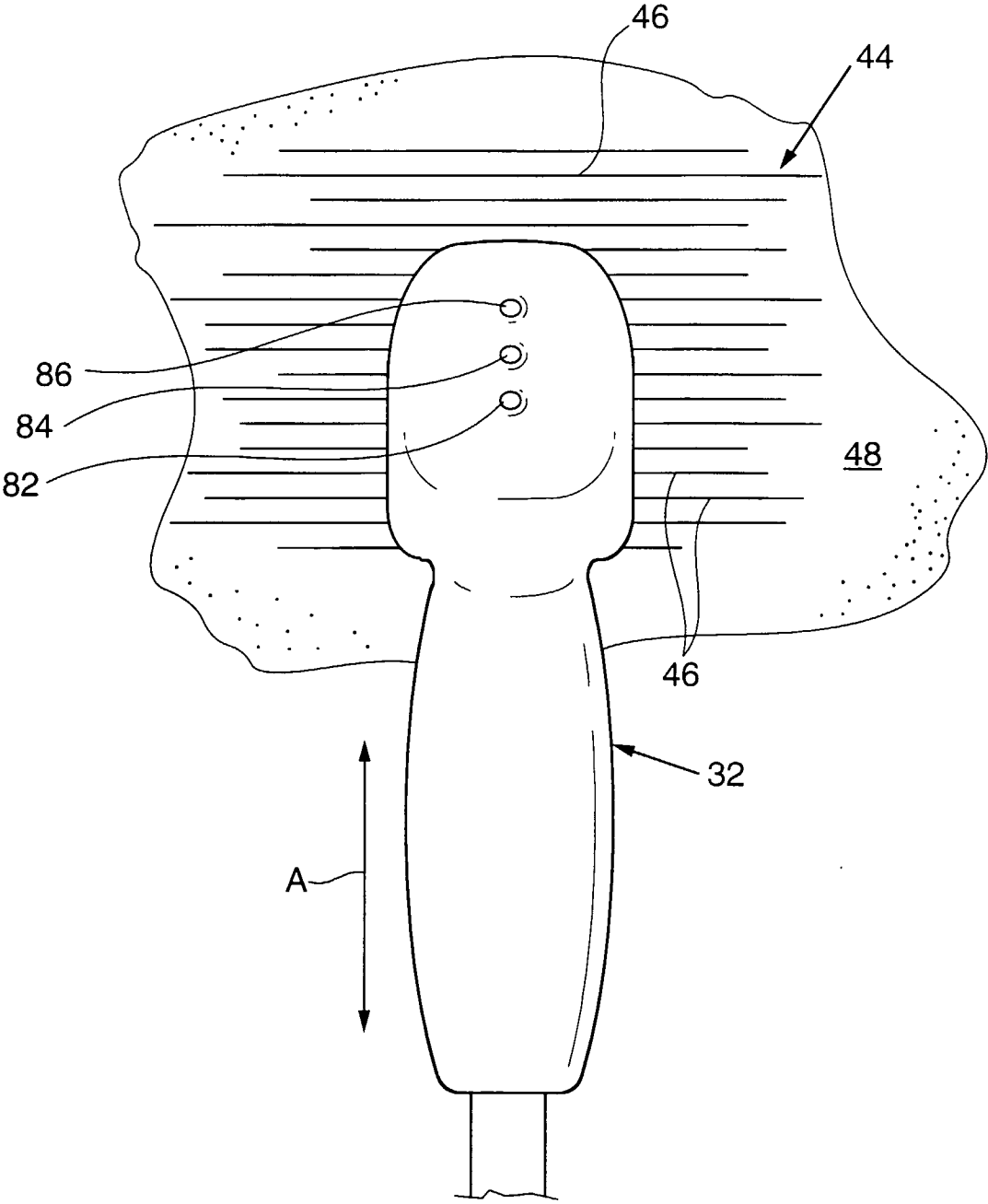


FIG. 2

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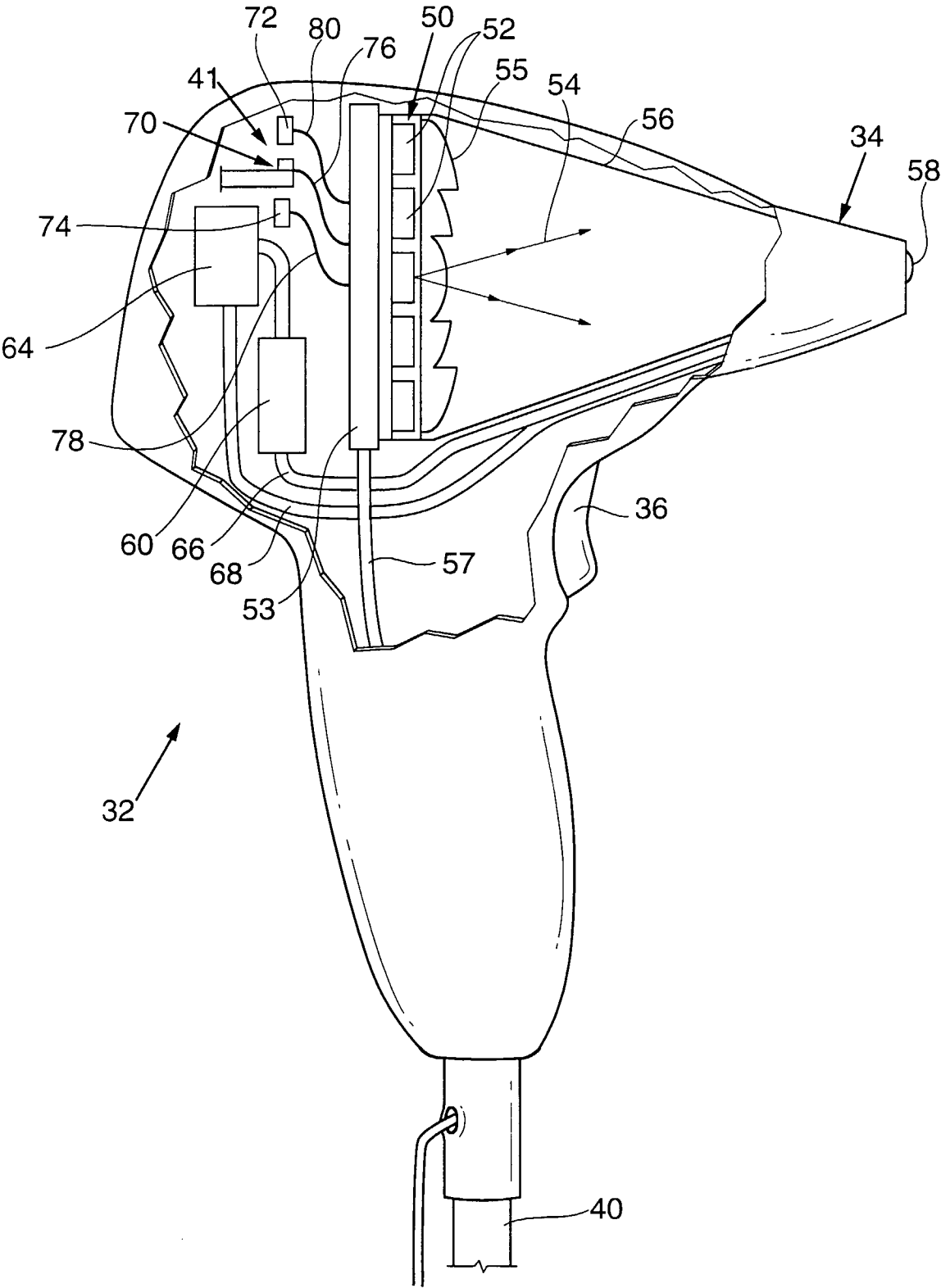


FIG. 3

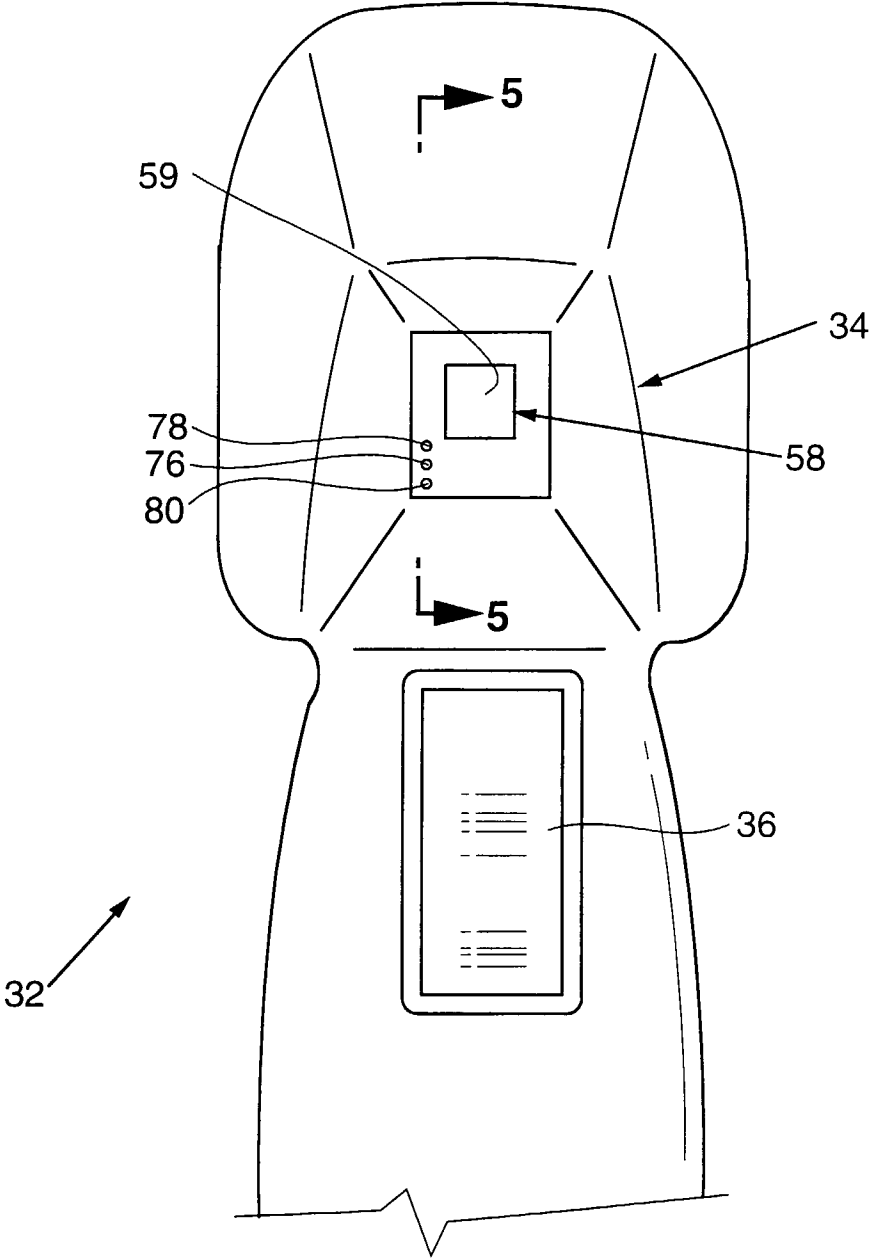
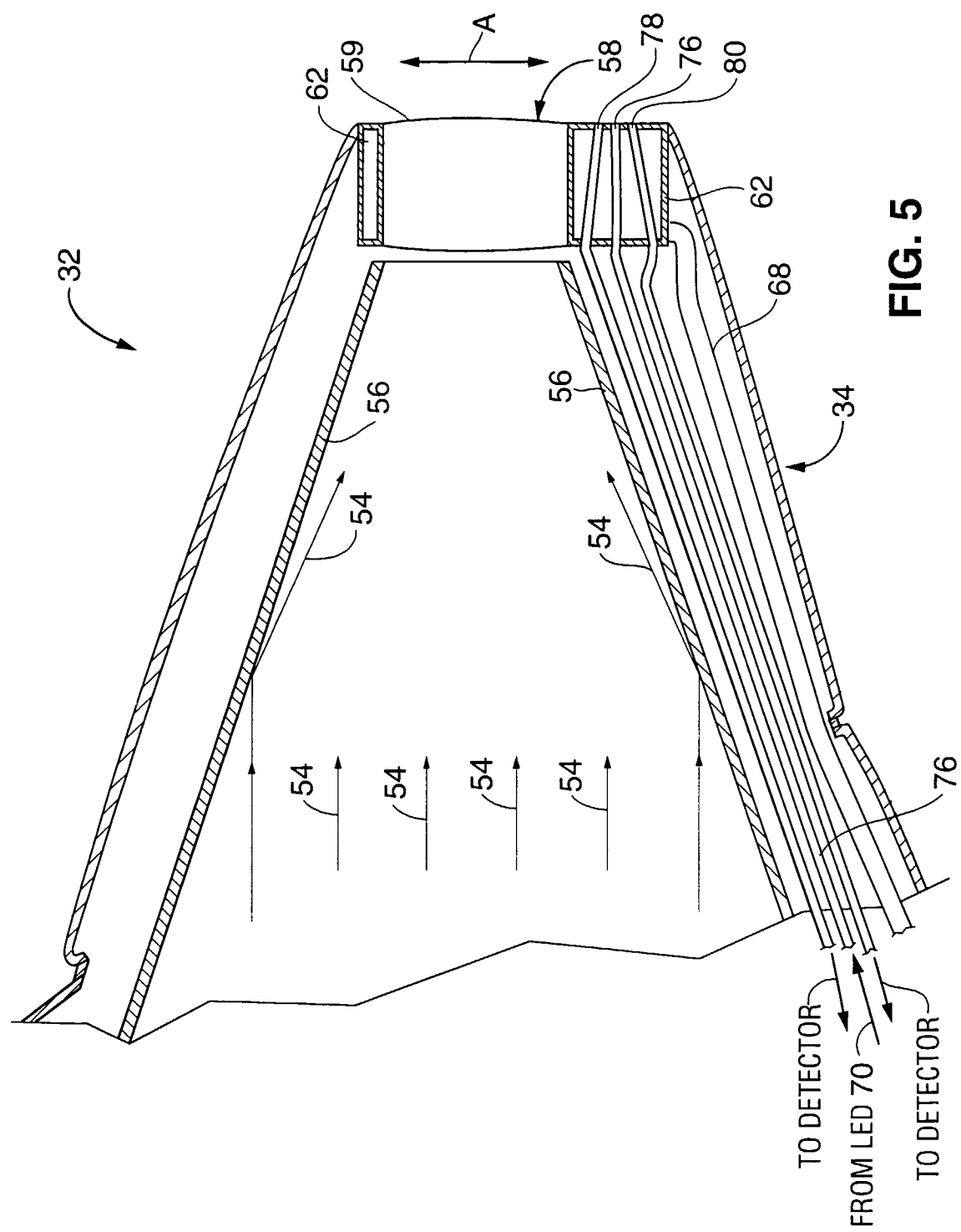


FIG. 4

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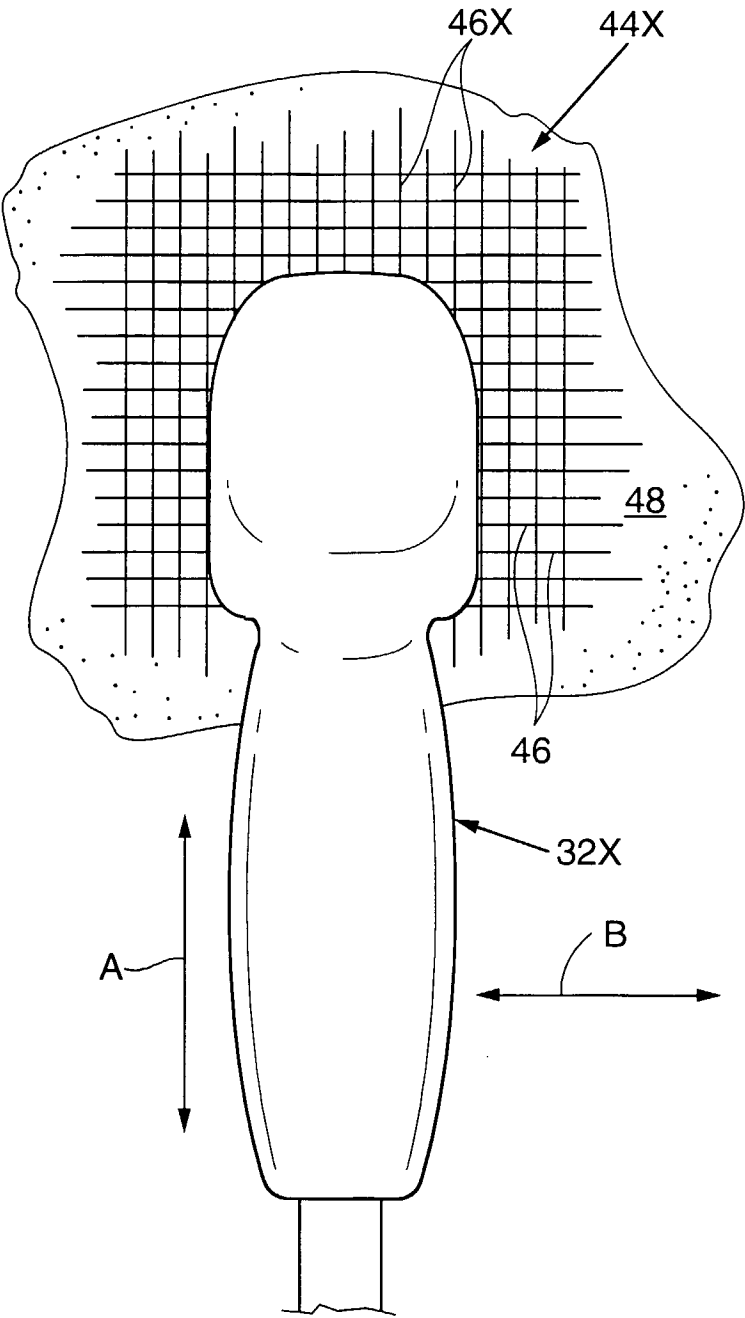


FIG. 6

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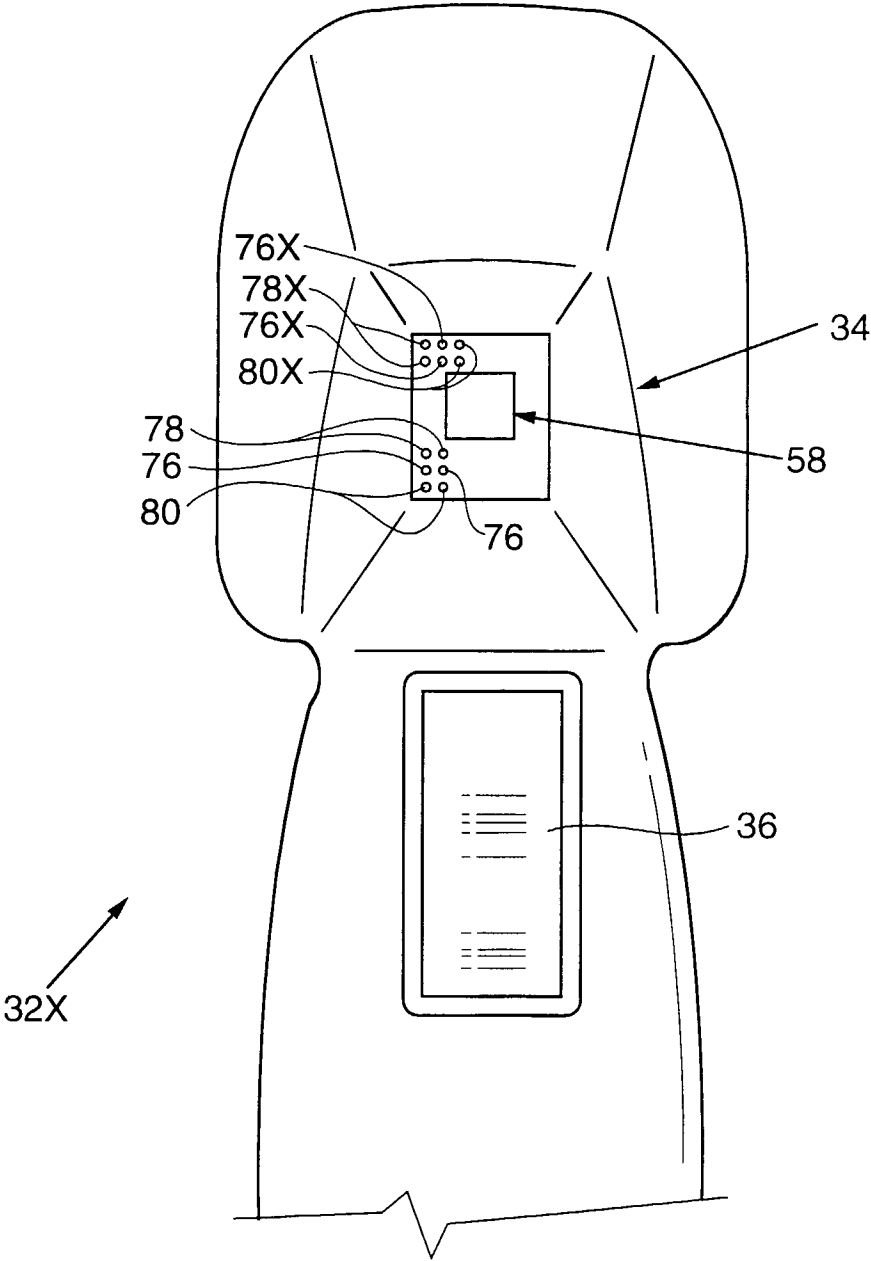


FIG. 7

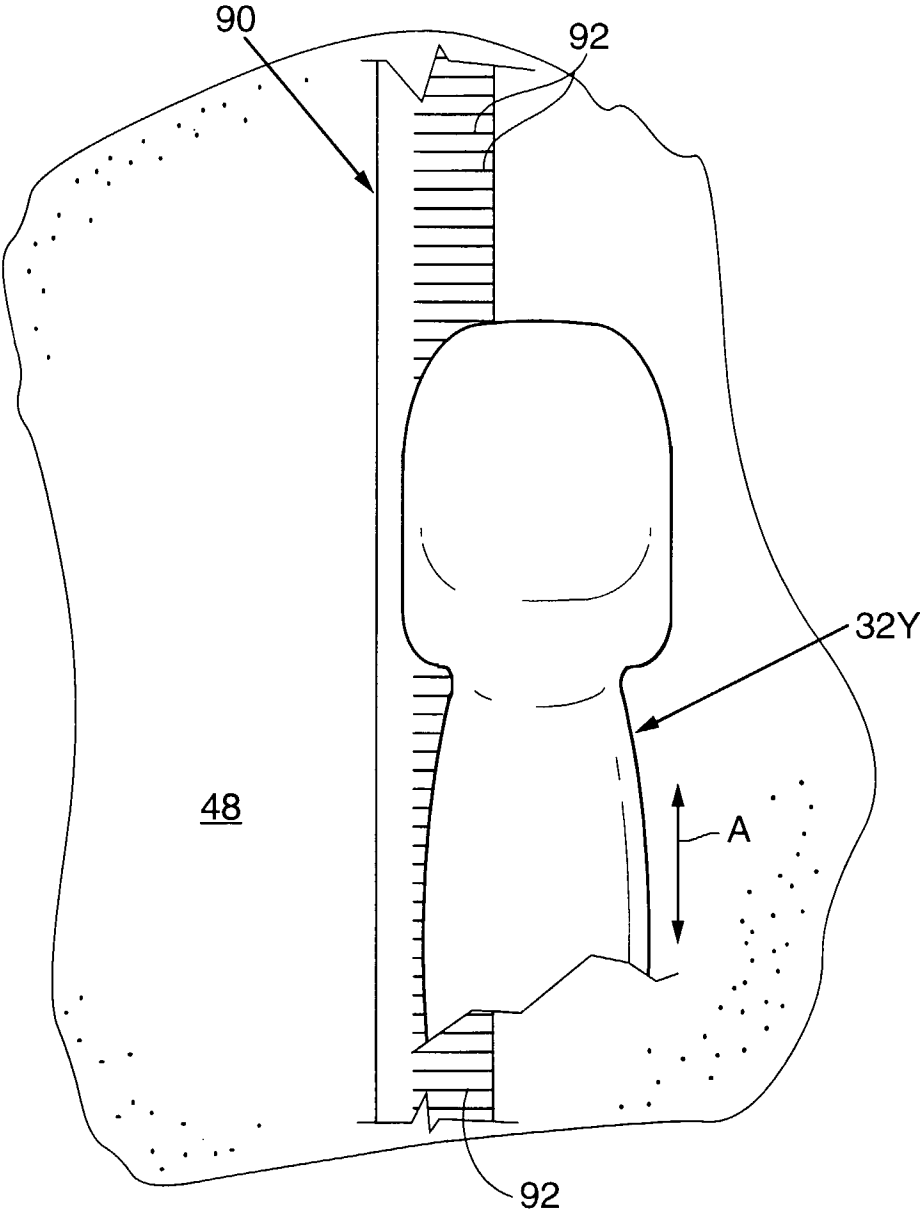


FIG. 8

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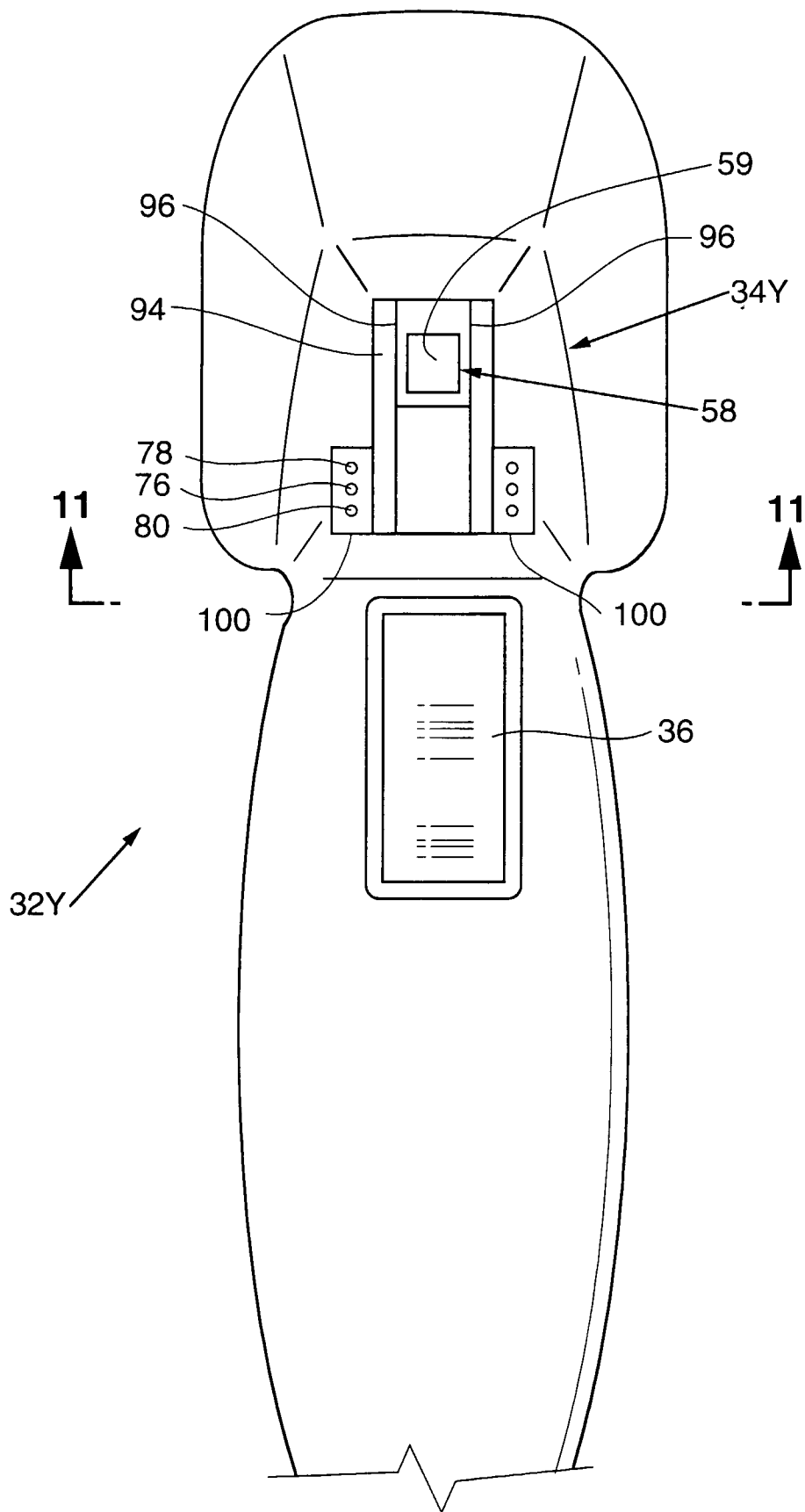


FIG. 9

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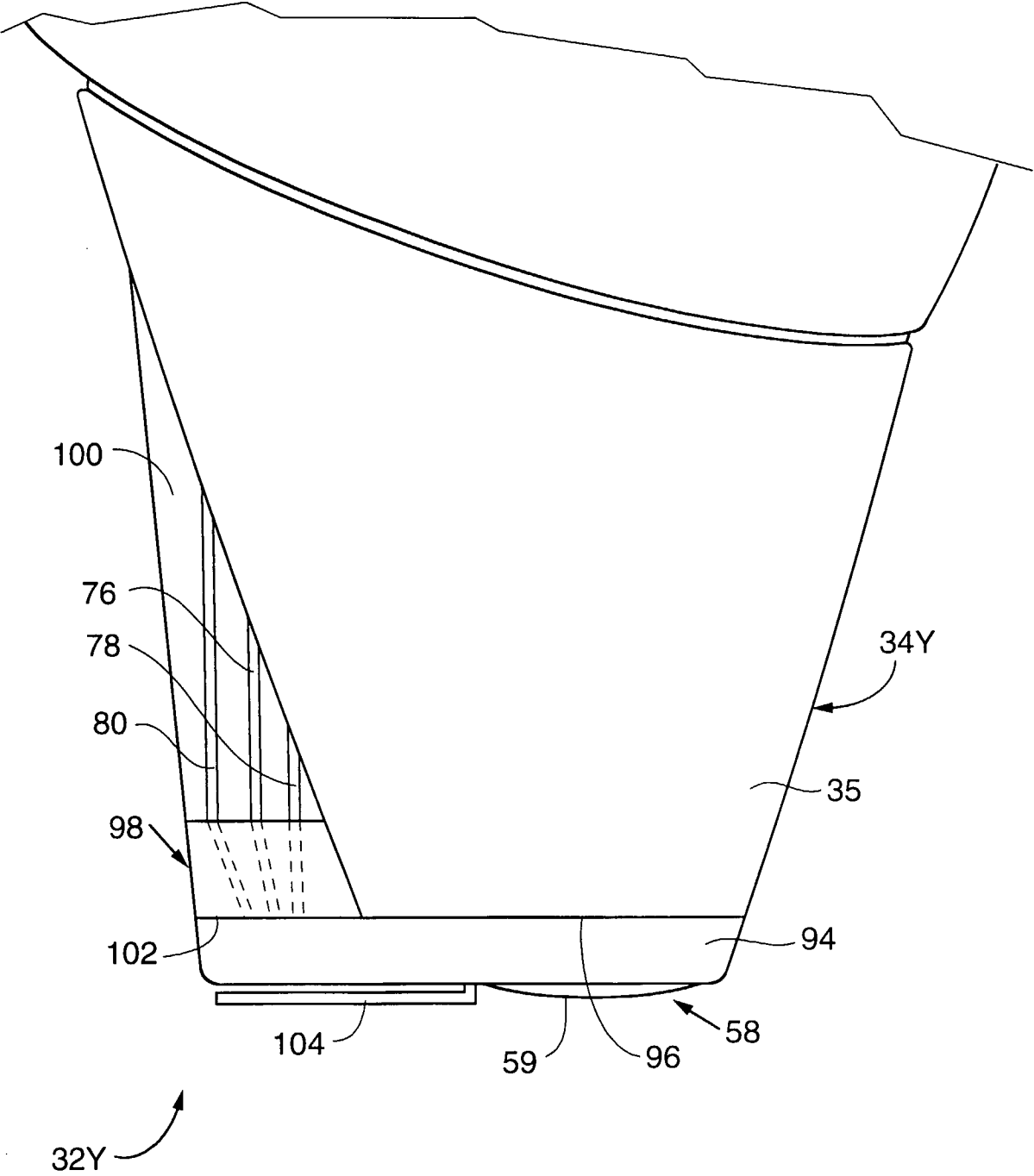


FIG. 10

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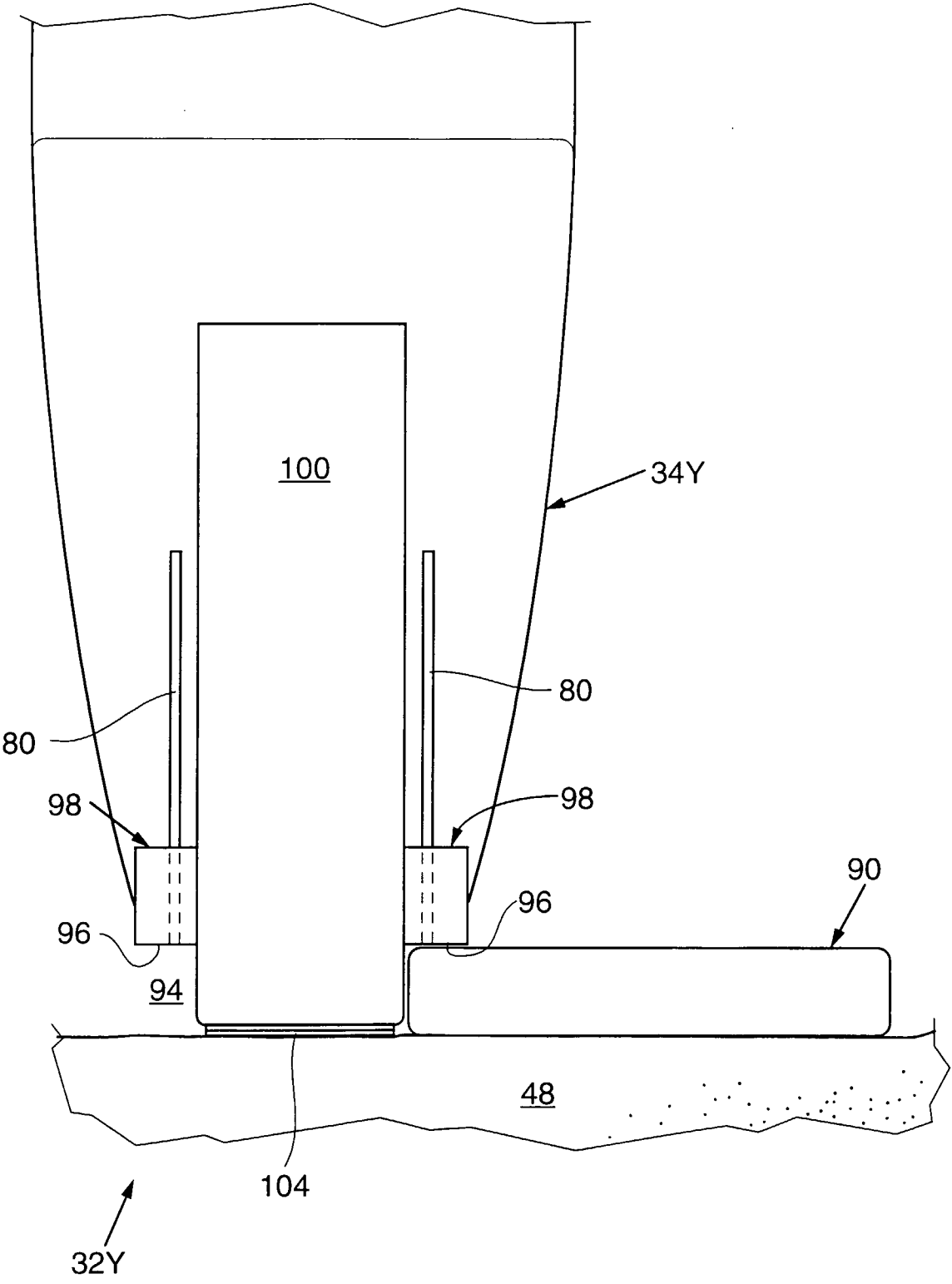


FIG. 11

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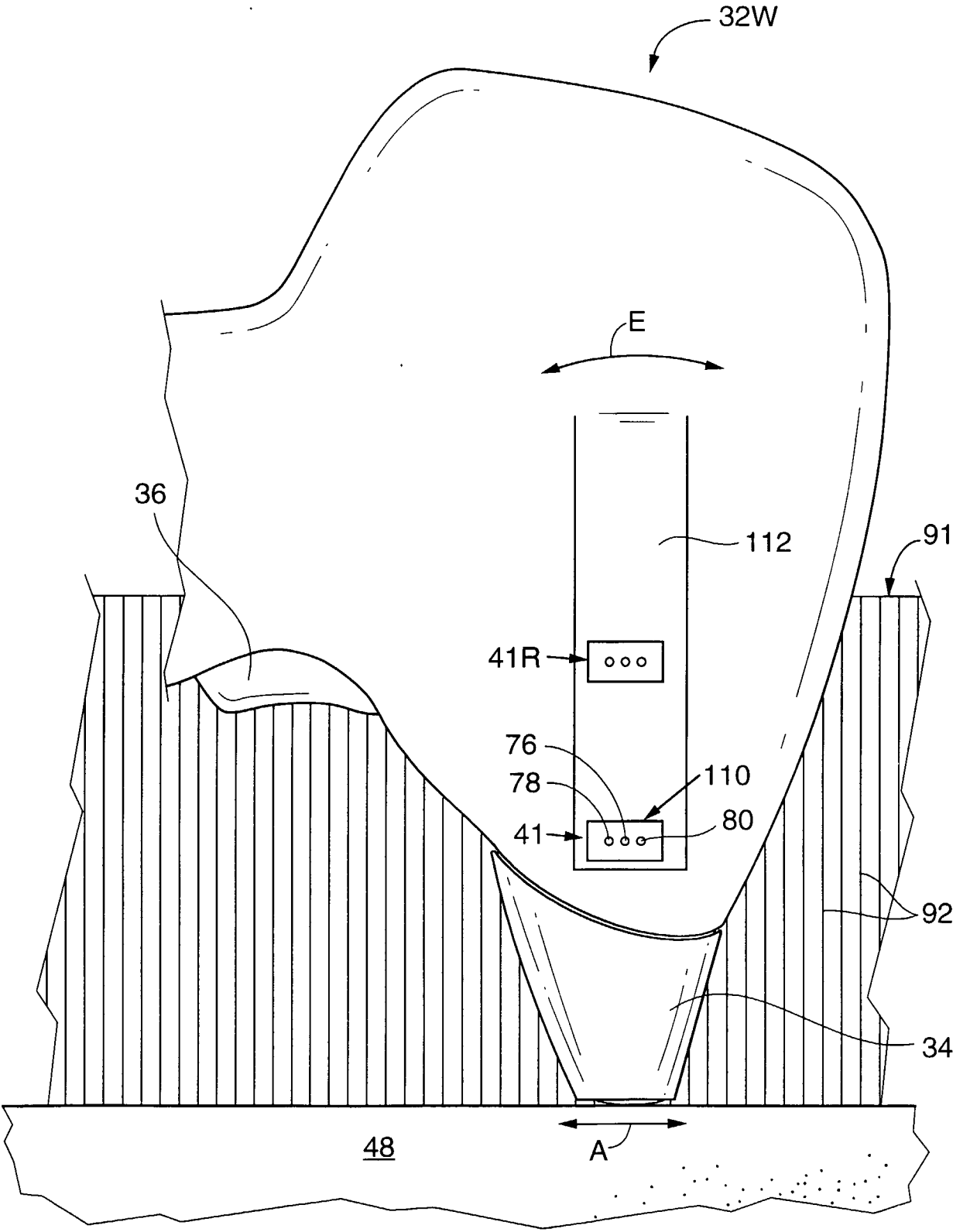


FIG. 12

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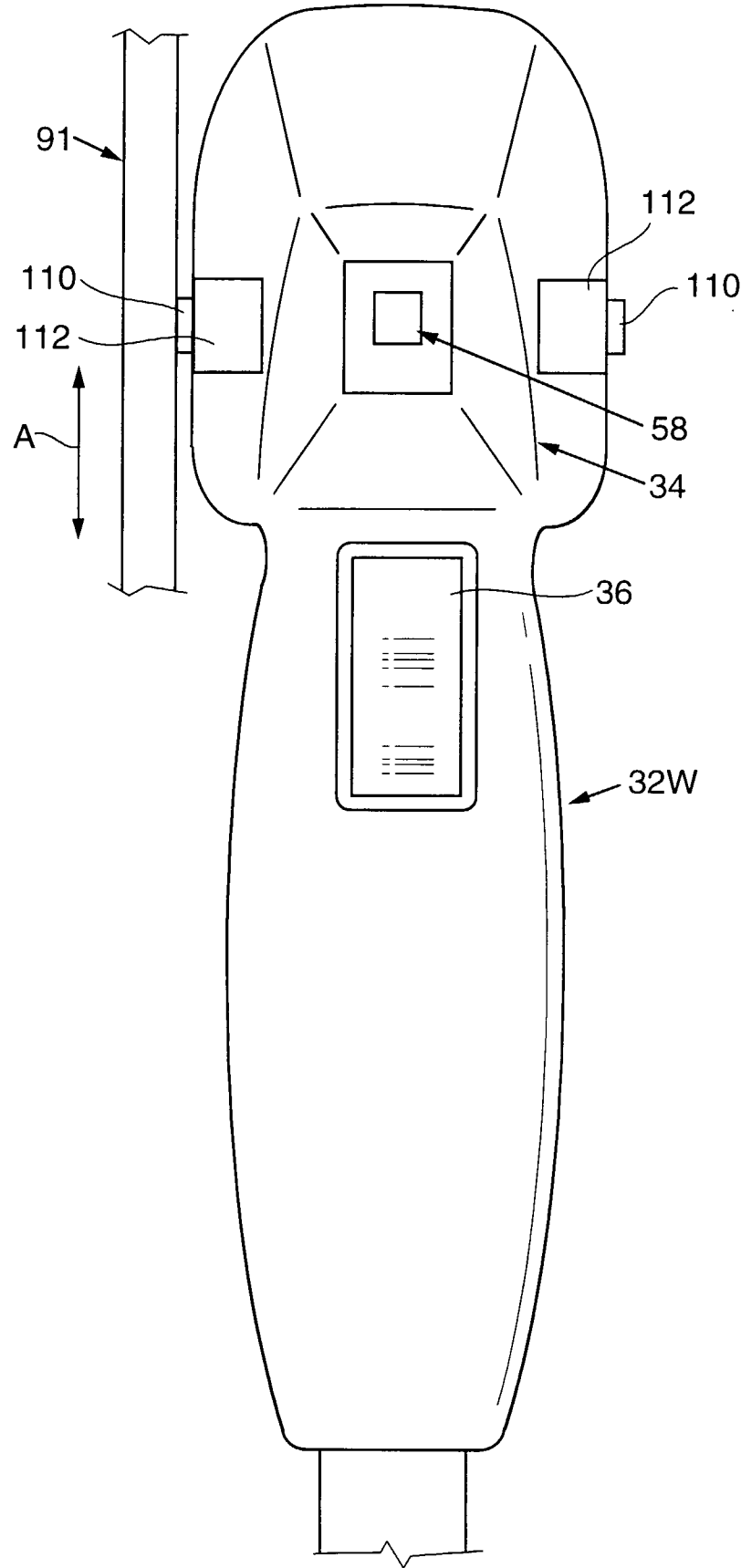


FIG. 13

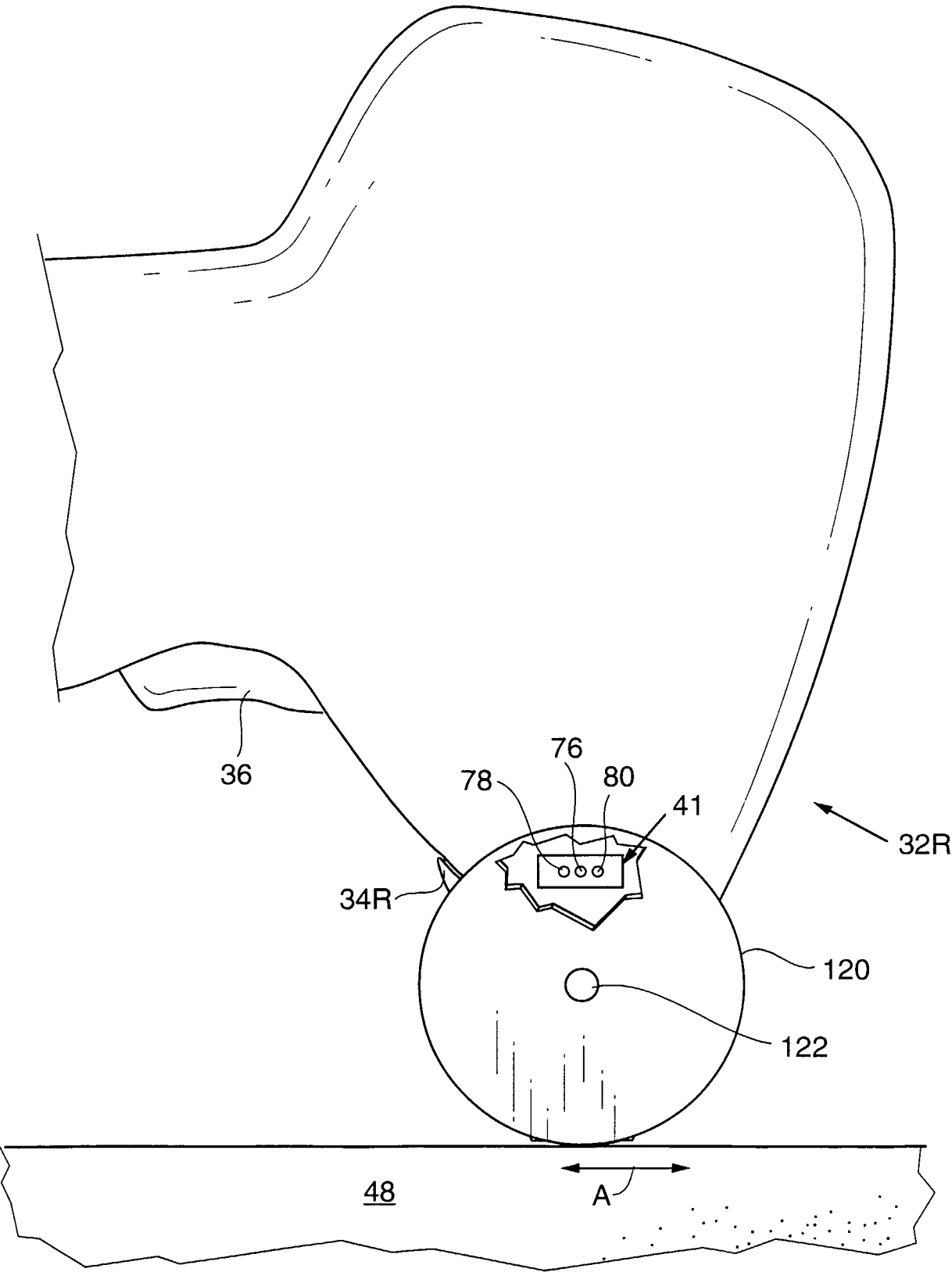


FIG. 14

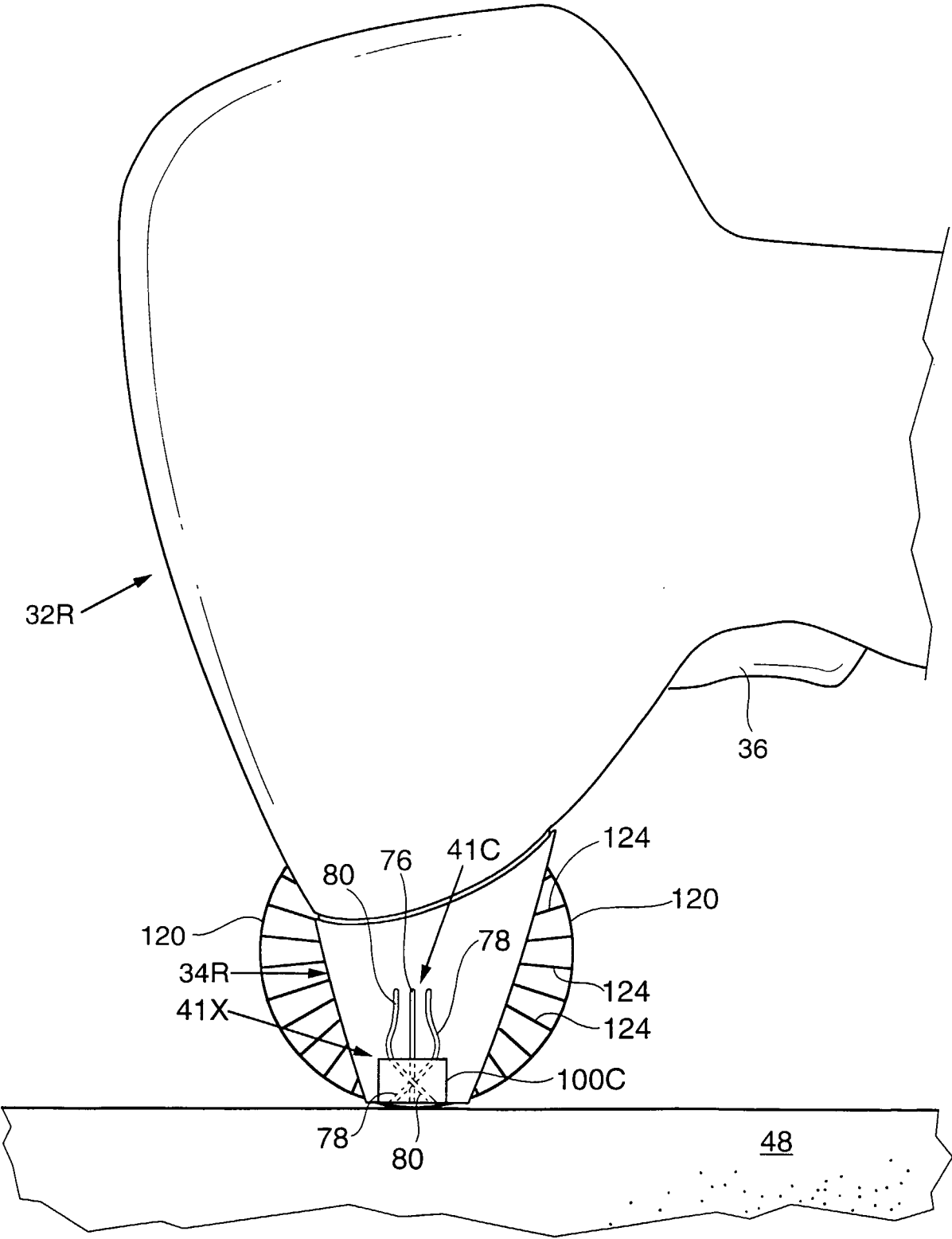
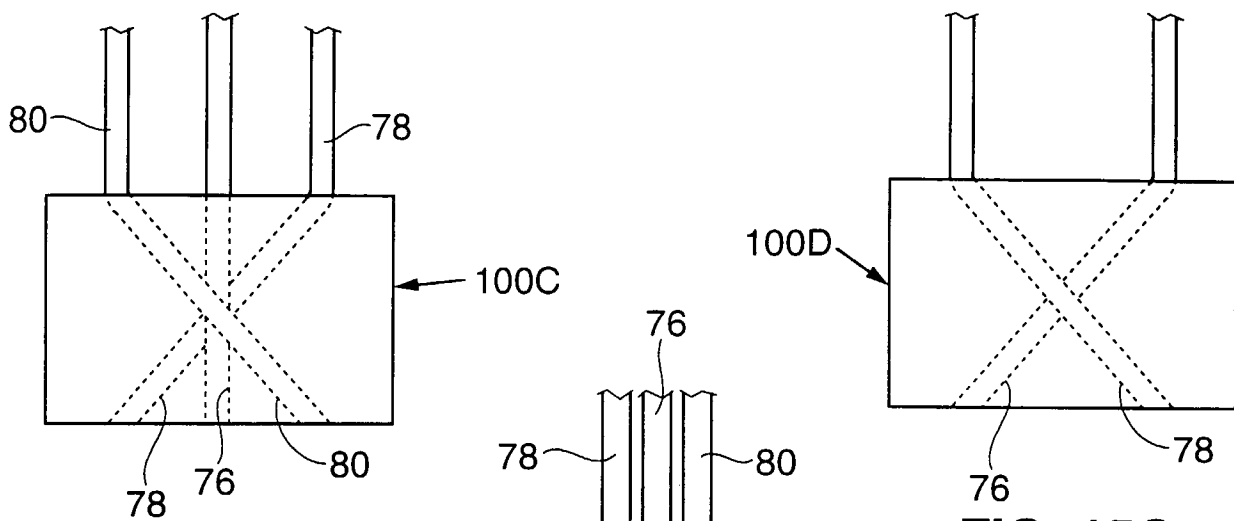
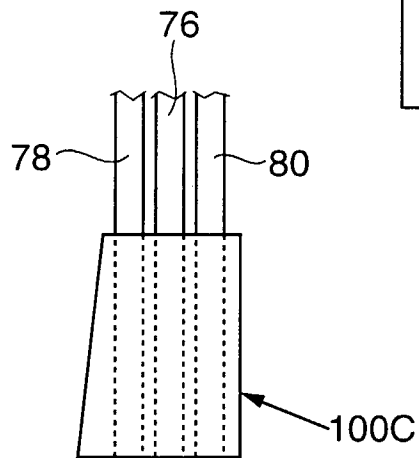
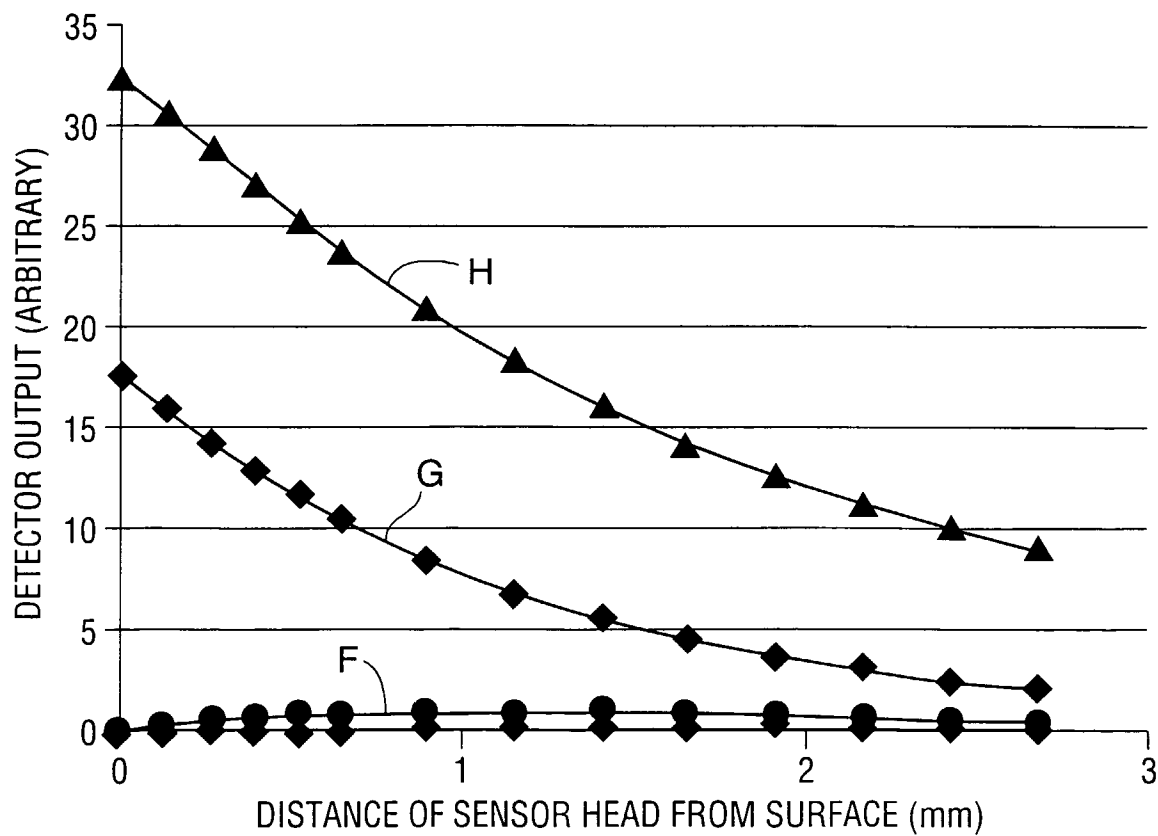


FIG. 15

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**FIG. 15A****FIG. 15C****FIG. 15B****FIG. 15D**

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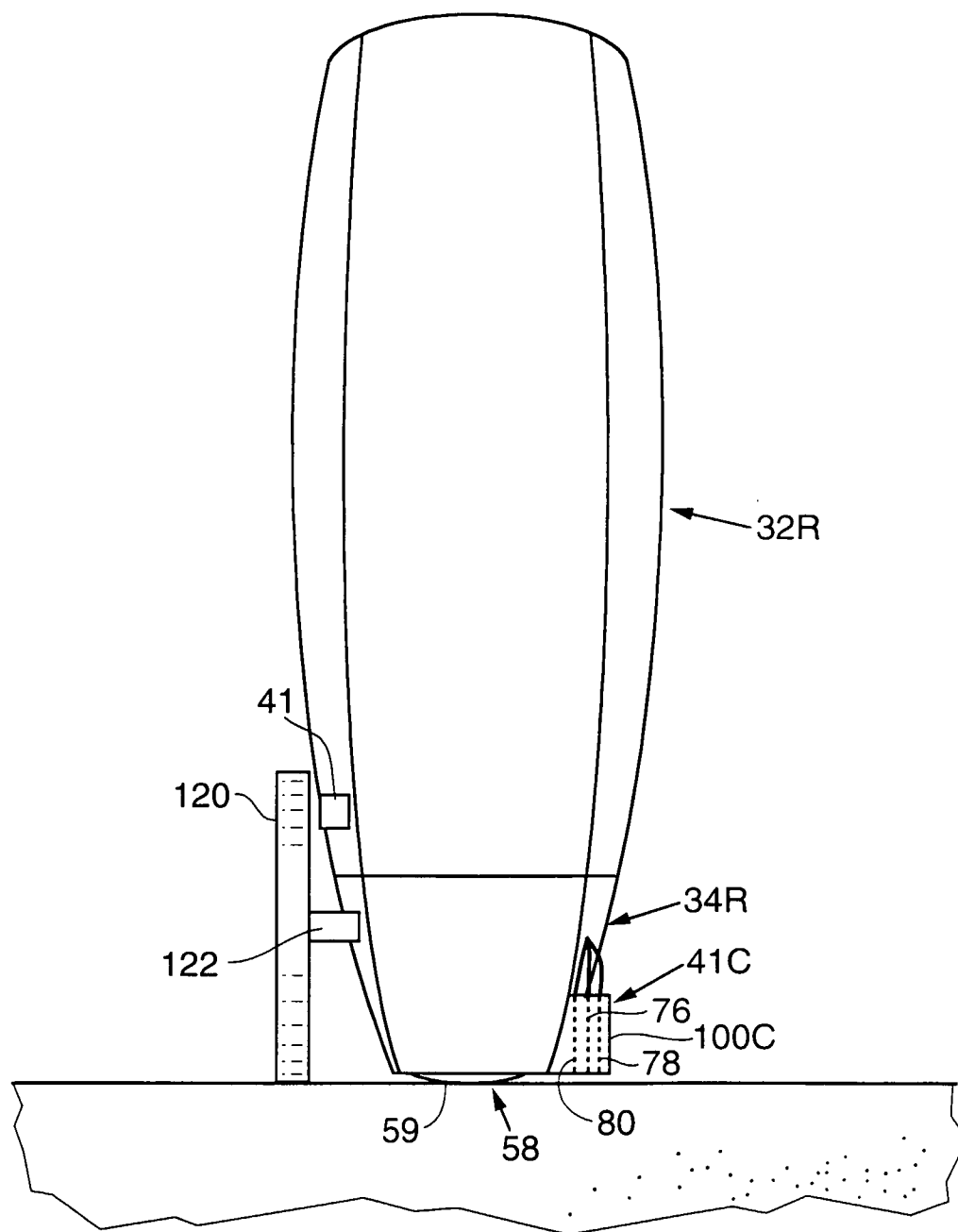


FIG. 16

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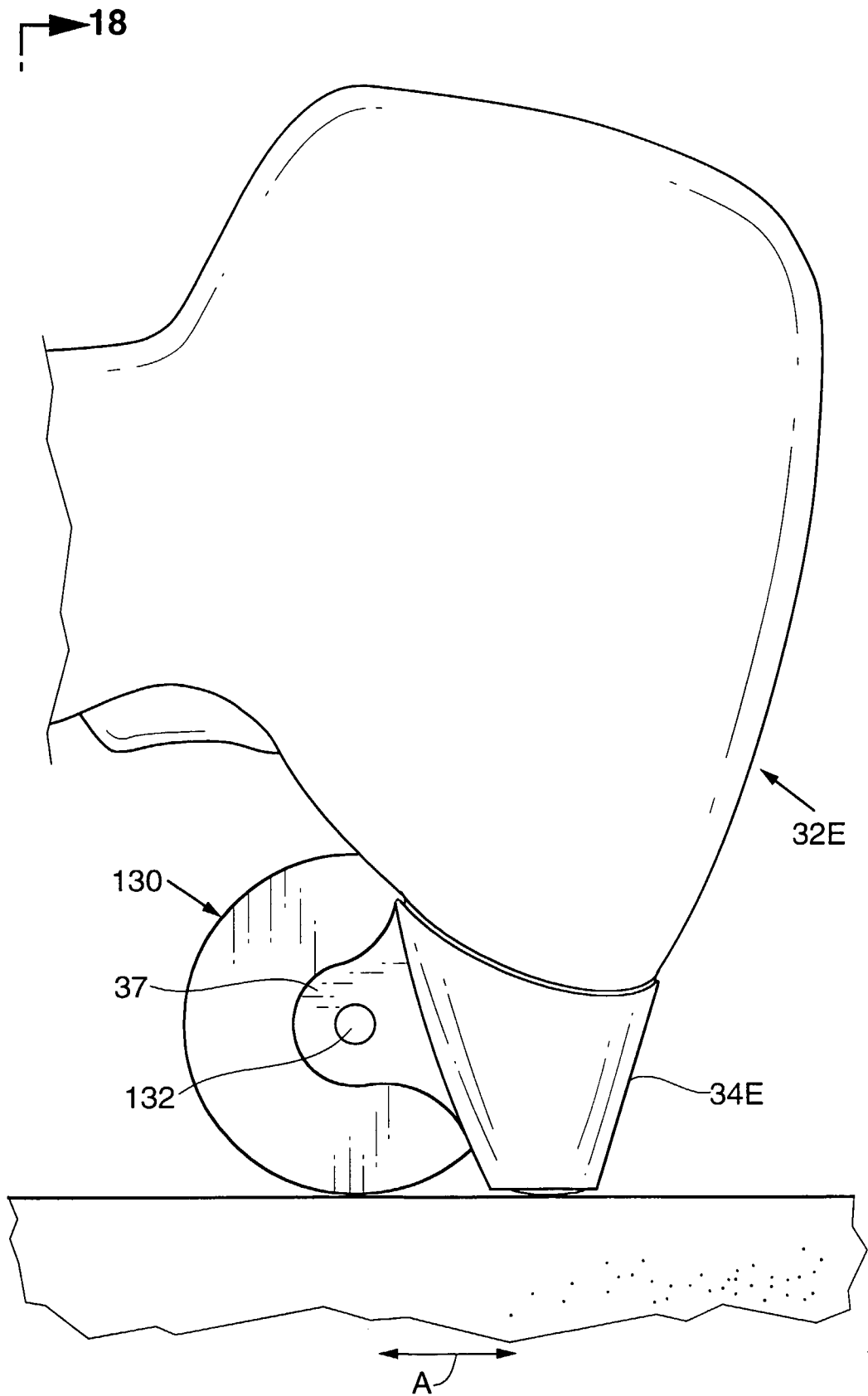


FIG. 17

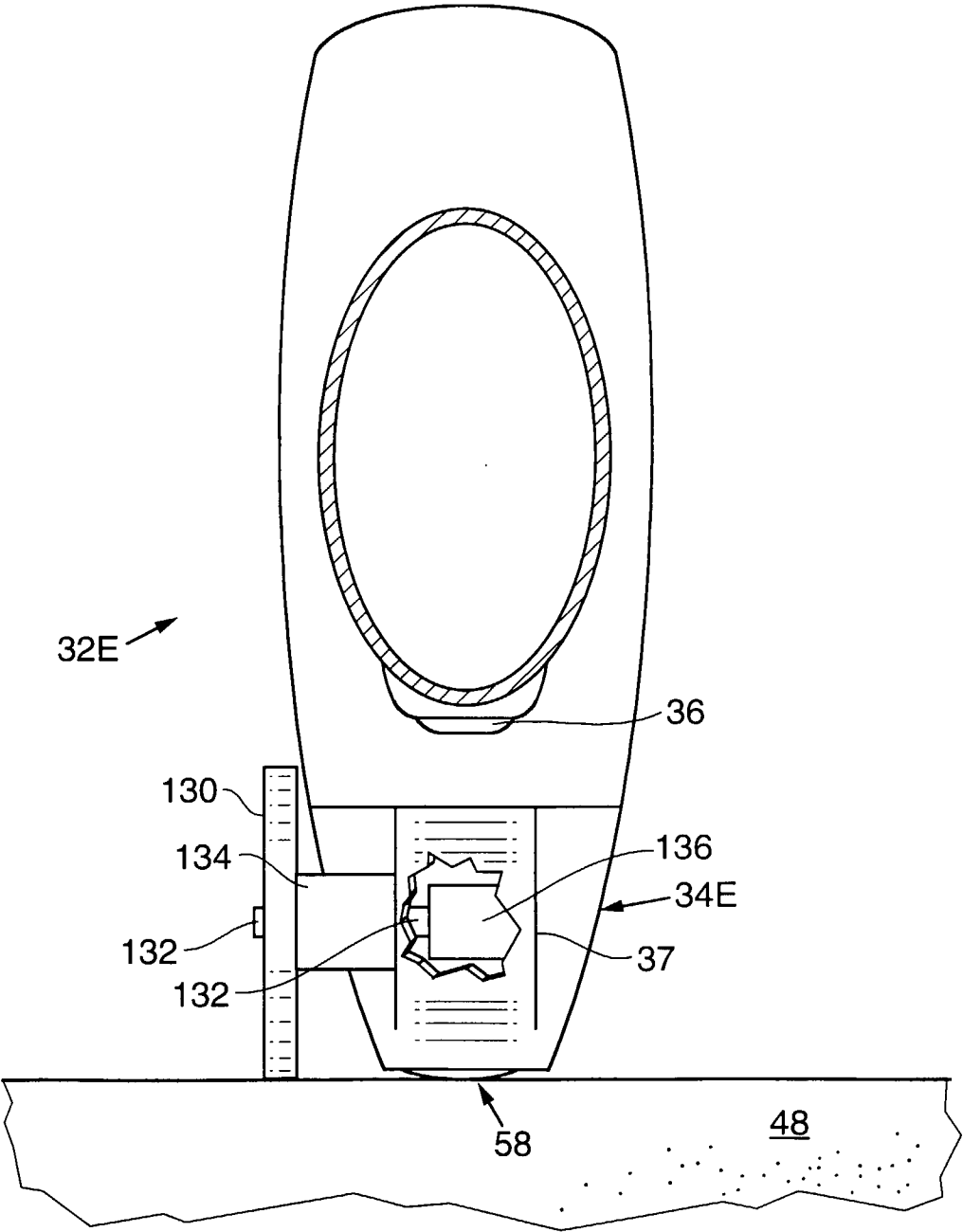


FIG. 18

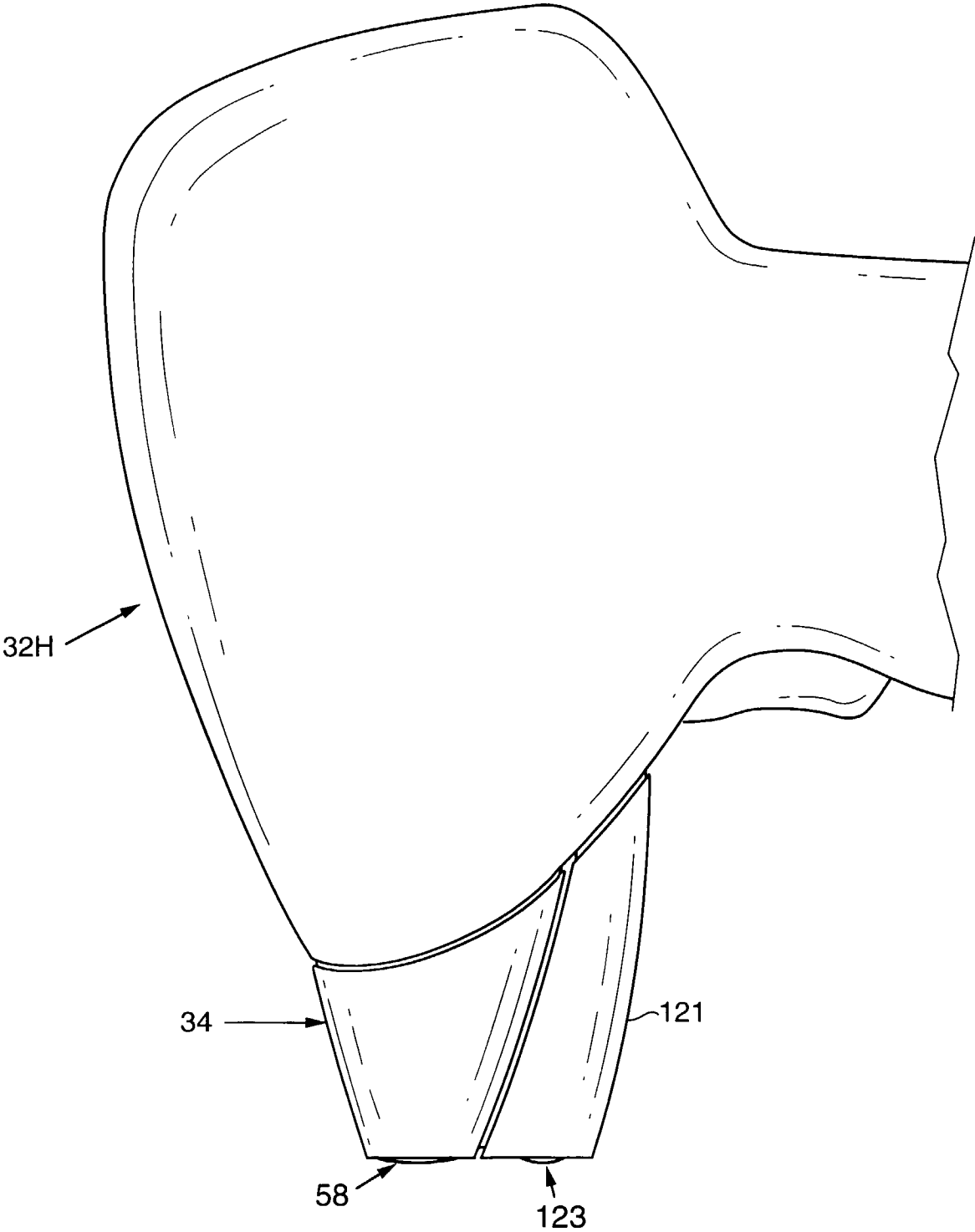


FIG. 19

FIG. 20

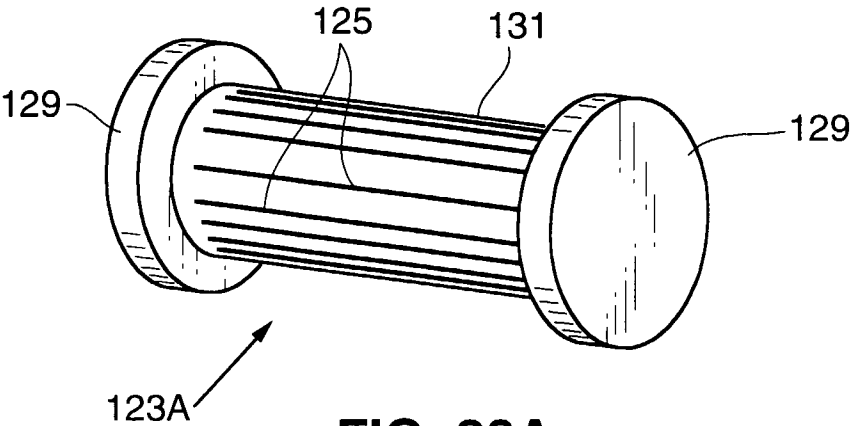
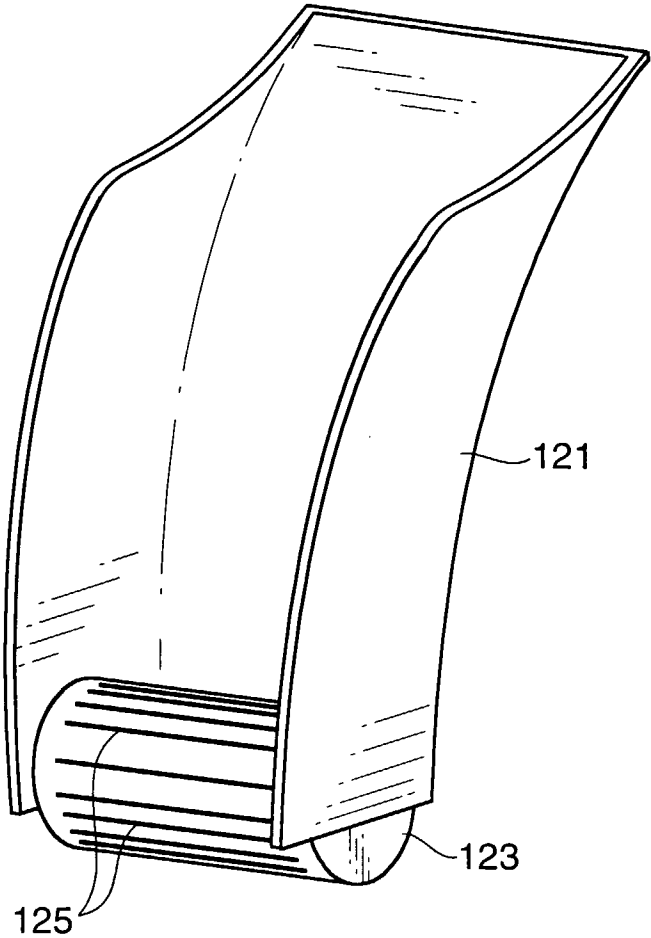


FIG. 20A

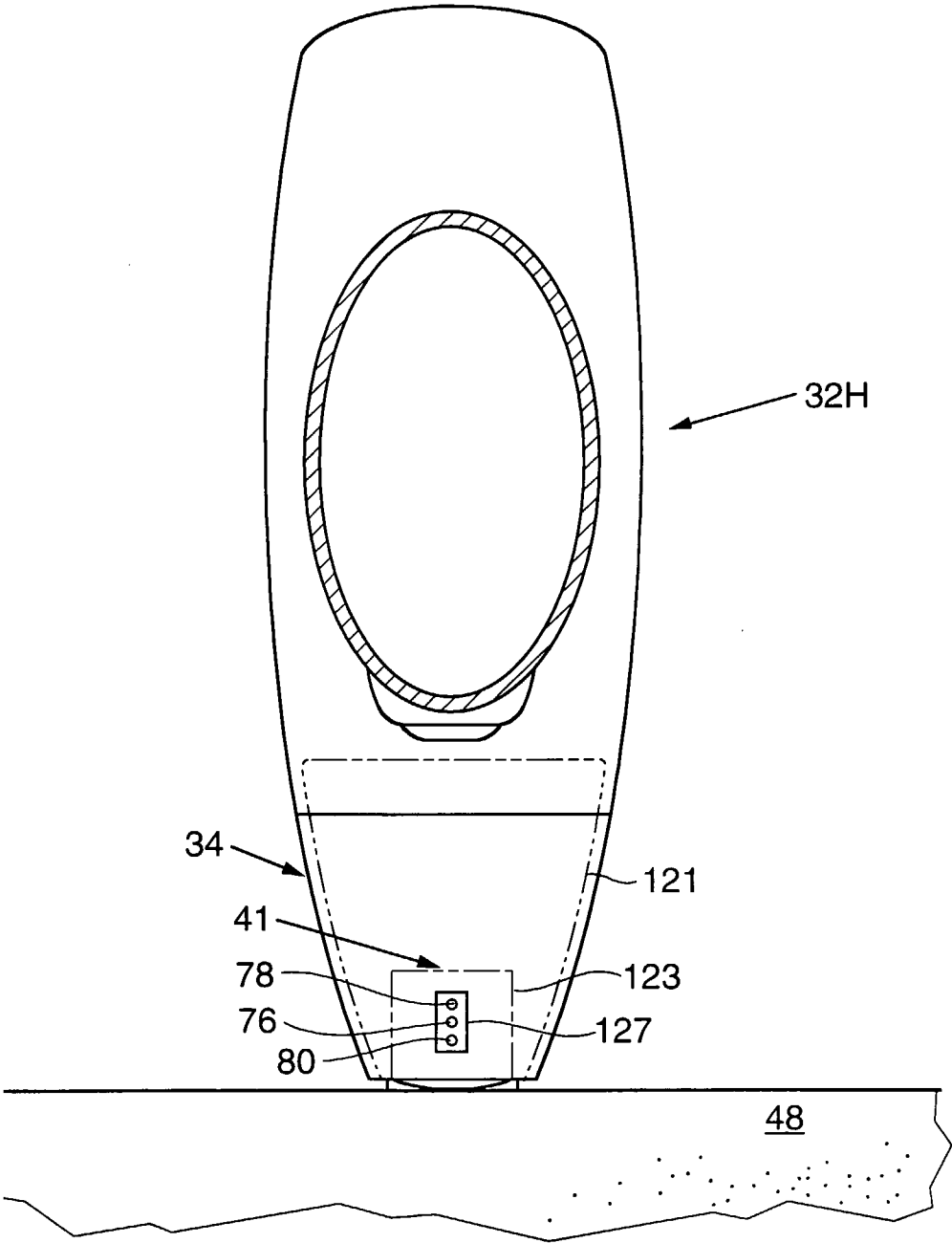


FIG. 21

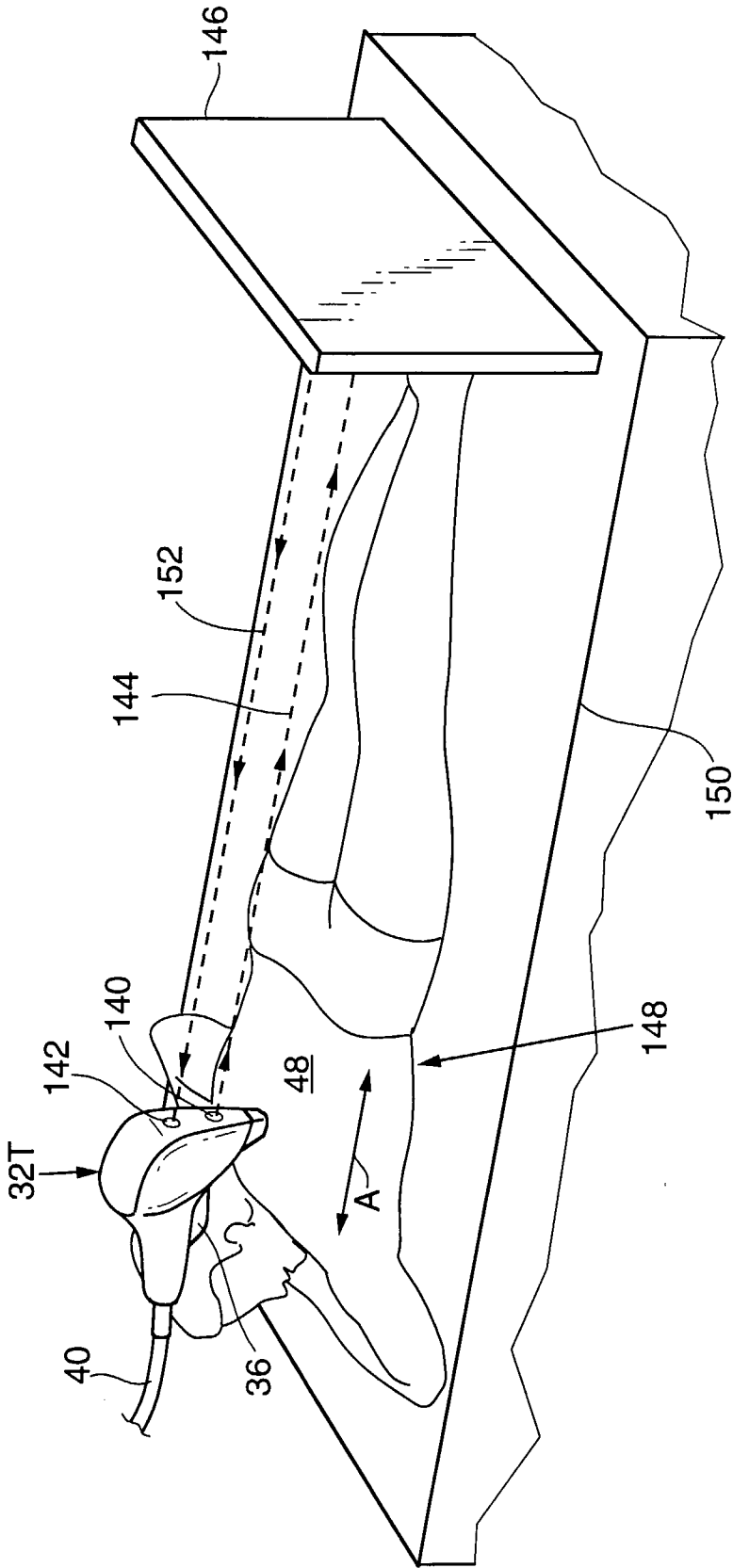


FIG. 22

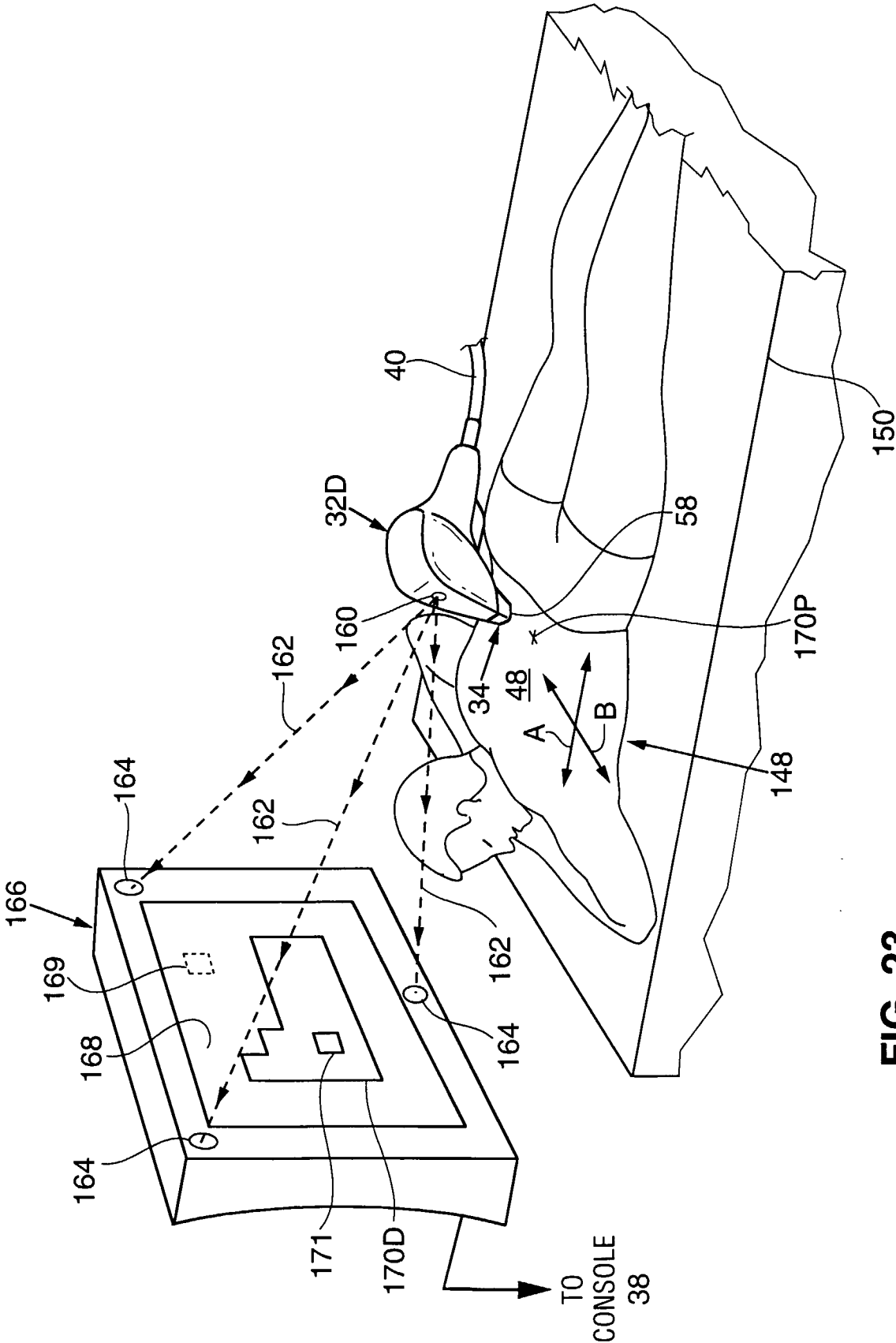


FIG. 23

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 51235 A (GEN HOSPITAL CORP ;PALOMAR MEDICAL TECHNOLOGIES I (US)) 19 November 1998 (1998-11-19) page 5, line 3 - line 19 page 8, line 23 - line 31 page 18, line 7 - line 18 page 20, line 3 - line 7; figure 9 ---	44, 49, 50
X	WO 99 11324 A (BALLE PETERSEN OLAV ;ASAH BJARNE (DK); ASAH MEDICO A S (DK); DOLLE) 11 March 1999 (1999-03-11) column 10, line 32 -column 12, line 21 ---	44-48
X	US 5 501 680 A (NARAYANAN KRISHNA ET AL) 26 March 1996 (1996-03-26) column 2, line 26 -column 3, line 20 column 7, line 38 - line 54 --- -/--	44-48



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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E earlier document but published on or after the international filing date

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

19 December 2000

Date of mailing of the international search report

28/12/2000

Name and mailing address of the ISA

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Authorized officer

Petter, E

INTERNATIONAL SEARCH REPORT

Internat Application No

PCT/US 00/26534

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 531 740 A (BLACK MICHAEL) 2 July 1996 (1996-07-02) abstract ----	44-48
A	WO 97 22384 A (LASER IND LTD) 26 June 1997 (1997-06-26) page 4, line 6 - line 22; figures 9A,9B page 11, line 16 -page 12, line 14 page 13, line 18 -page 14, line 13 page 10, line 23 - line 26 ----	44-48
A	EP 0 898 983 A (NIDEK KK) 3 March 1999 (1999-03-03) column 3, line 55 -column 4, line 19 column 4, line 29 - line 46 column 9, line 39 - line 54 -----	44-50

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internz Application No

PCT/US 00/26534

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9851235	A	19-11-1998	AU 7568698 A EP 0991372 A	08-12-1998 12-04-2000
WO 9911324	A	11-03-1999	AU 8851898 A EP 1009485 A US 6074382 A	22-03-1999 21-06-2000 13-06-2000
US 5501680	A	26-03-1996	NONE	
US 5531740	A	02-07-1996	NONE	
WO 9722384	A	26-06-1997	AU 704892 B AU 1071097 A BR 9612145 A EP 0874666 A US 5868732 A US 5879346 A GB 2308307 A	06-05-1999 14-07-1997 13-07-1999 04-11-1998 09-02-1999 09-03-1999 25-06-1997
EP 0898983	A	03-03-1999	JP 11070121 A US 5971978 A	16-03-1999 26-10-1999

**(19) World Intellectual Property Organization
International Bureau**



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PCT

(10) International Publication Number
WO 01/34048 A1

(51) International Patent Classification⁷: A61B 18/20

(72) Inventors: ALTSHULER, Gregory, B.; 8R Fernbanks Road, Wilmington, MA 01887 (US). ZENZI, Henry, H.; 145 High Street, Chelmsford, MA 01824 (US).

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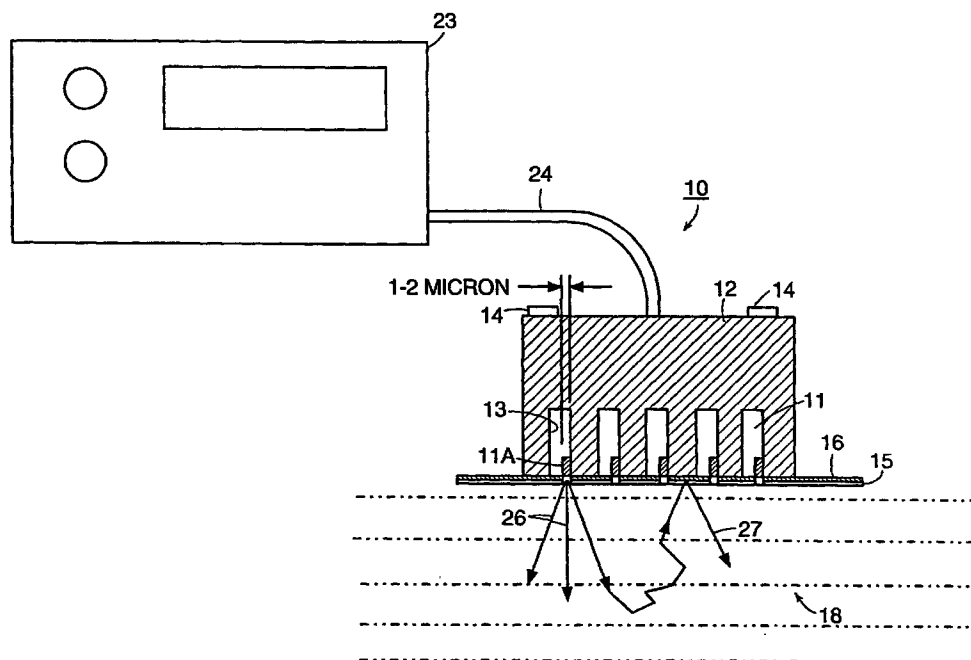
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(54) Title: LIGHT ENERGY DELIVERY HEAD



(57) Abstract: A light energy delivery head is provided which, in one aspect, mounts laser diode bars or other light energy emitters in a heat sink block which is adapted to cool both the emitters and a surface of a medium with which the head is in contact and to which it is applying light energy. In another aspect, various retroreflection configurations are provided which optimize retroreflection of back-scattered light energy from the medium. The size of the aperture through which light energy is applied to the medium is also controlled so as to provide a desired amplification coefficient as a result of retroreflection.

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LIGHT ENERGY DELIVERY HEAD

Prior Applications

This application is a continuation-in-part of application serial number 09/078,055, filed May 13, 1998, which application claims priority from provisional specification 60/046,542, filed May 15, 1997 and 60/077,726, filed March 12, 1998. This application also claims priority from provisional specification 60/115,447, filed January 8, 1999 and
5 from provisional specification 60/164,492, filed November 9, 1999. The contents of all of these prior application specifications are incorporated herein by reference.

Field of the Invention

This invention relates to light energy delivery heads, and more particularly to a laser
10 diode head or other light energy delivery head for delivering light energy to a selected depth in a medium, particularly a scattering medium, which head provides improved heat management for both the laser diodes (or other light energy emitter) and the medium and/or which more efficiently utilizes light energy from the laser/emitter.

Background of the Invention

15 Light energy emitters, including lasers, and in particular semiconductor diode lasers, flash lamps, halogen and other filament lamps, etc., are finding increasing application in medical, industrial, research, governmental and other applications. For many of these applications, the light energy is to be delivered at a selected depth in a light scattering
20 medium. Because of the scattering, only a fraction of the light energy delivered to the surface of the medium reaches the target area, with much of the remaining energy being refracted out of the medium and dissipated in the surrounding atmosphere. For a highly scattering medium such as skin, as much as 50-80 percent of the incident energy may be lost due to this back scattering effect, requiring more powerful light energy emitters/lasers or a larger number of
25 emitters/diode lasers (where diode lasers are used), or requiring that light energy be delivered over a much smaller area, in order to achieve a desired fluence at a target. Utilizing a head with a more powerful emitter/laser or utilizing a larger number of and/or more powerful emitters/diode lasers makes the head larger and more expensive and increases the heat

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management problems resulting from use of the head. Concentrating the beam to achieve higher fluence with smaller spot size or aperture adversely affects the depth in the medium which can be reached by the light energy and can significantly increase the time required to perform a given procedure.

5 U.S. Patent No. 5,824,023, to Rox Anderson, teaches one way of dealing with the reflection problem with certain laser or other light energy emitting devices. However, the technique of this patent also results in small spot sizes and is not readily adaptable for use in certain applications, such as in laser diode heads. An improved technique is therefore required to permit optimum utilization of the light energy from light energy emitting devices
10 in general, and from laser diodes or laser diode bars of a laser diode head in particular, by recycling or reusing light scattered from the surface of the irradiated medium and directing it back toward a desired target area in the medium.

A related problem involves heat management when using a laser diode head, or other head containing light energy emitters, and in particular the ability to utilize a common cooling
15 element to cool both the laser diodes/light energy emitters and the surface of the medium being irradiated. Surface cooling can be required in various applications, particularly medical applications, since laser energy being delivered at a depth in the medium, for example a patient's skin, must pass through the surface of the medium, for example the epidermis of a patient's skin, in order to reach the target area. Heating of the medium surface can cause
20 damage at the surface if suitable cooling is not provided. Prior art systems have either not provided cooling for the medium surface or have required separate cooling elements for the diodes and the medium.

Summary of the Invention

25 In accordance with the above, this invention provides, in a first aspect, a head for applying light energy to a selected depth in a scattering medium having an outer layer in physical and thermal contact with the head. The head includes a thermally conductive block or mount having an energy emitting surface; at least one laser diode or other energy emitting element mounted in the block adjacent the energy emitting surface, each of the elements being
30 in thermal contact with the mount and being oriented to direct light energy through the energy emitting surface. A thin, transparent, thermally conductive layer is provided over the light

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emitting surface and in thermal contact therewith, the layer being in contact with the outer layer of the medium when the head is applying light energy thereto. Finally, a cooling mechanism is provided for the mount, permitting the mount to sink heat from both the elements and the outer layer of the medium. For some embodiments, the thermally
 5 conductive layer is a coating formed on the light emitting surface of the mount.

For preferred embodiments, the head also includes a reflecting layer formed on the thermally conductive layer, which reflecting layer has an opening formed therein under each element through which light energy may be applied to the medium. The reflecting layer is preferably between the thermally conductive layer and the energy emitting surface of the
 10 mount/block, and preferably has an area larger than the area of the block. In particular, the area of the reflecting layer could be at least substantially as large as the aperture of reflection for scattered light energy from the medium. In order to achieve a desired amplification coefficient (f) as a result of retroreflection from the reflecting layer, the aperture through

$$D_{\min} = \frac{d}{\sqrt{\frac{f \cdot R \cdot r}{f - 1} - 1}}$$

which light energy is applied to the medium should have a minimum dimension

15 where d is a back-scatter aperture increment for a given wavelength and medium, R is the reflection coefficient of the medium and r is the reflection coefficient of the reflecting layer.

The block for the laser diode head may assume a variety of forms. In particular, for some embodiments of the invention, the block has a depression formed therein, with the energy emitting surface being the surface of the depression, and with each of the elements for
 20 some embodiments being mounted to emit light energy substantially perpendicular to the depression surface at the point thereon where the element is mounted. The medium is forced into the depression and into contact with the surface thereof. The forcing of medium into the depression may be accomplished by merely pressing the head against a soft deformable medium, such as some areas of a person's skin, or suction, for example a vacuum line, may
 25 be provided to draw the skin or other medium into the depression. The depression may have a variety of shapes, including being substantially semi-cylindrical or substantially rectangular. Where the head is being utilized for hair removal on for example a person, the depression

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may be of a size sufficient to permit a single hair follicle to enter the depression in the plane of the rectangular depression.

The reflecting layer may also be formed and utilized for heads which use the cooled block to cool the diodes or other light energy emitters only and not to cool the surface of the medium, for example in applications where a thicker transparent layer is employed or for heads using light energy emitting elements other than laser diode bars, for example filament lamps or light pipes fed by a suitable light emitting component. For such heads, the reflecting layer would still have areas of the type indicated above and would preferably have an emitting aperture with a minimum dimension D_{\min} determined as indicated above. For these embodiments, the transparent layer could be a waveguide of selected shape, which shape could be a truncated shape which, depending on desired aperture size, would have either its larger end or shorter end adjacent the block. Selected sides or walls of the waveguide may have an angle dependent reflecting layer to attenuate sharply angled light energy entering the waveguide.

In still another aspect of the invention, the head may include at least one energy emitting element mounted to apply light energy to the medium through an aperture, which aperture has a minimum dimension D_{\min} defined as indicated above, and a reflecting layer mounted to retroreflect light energy back-scattered from the medium. The aperture may be circular, with D being a diameter of the aperture, or substantially rectangular, with D as the length of a short side of the aperture.

The foregoing and other objects, features and advantages of the invention will be apparent from the following more specific description of preferred embodiments of the invention as illustrated in the accompanying drawings.

In the Drawings

Fig. 1 is partially cutaway, side elevation, semi-schematic representation of a head in accordance with a first embodiment of the invention;

Figs. 2A and 2B are enlarged side elevation views of a portion of the head shown in Fig. 1 for two different species thereof;

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Fig. 3A is a cutaway, side elevation, semi-schematic representation of a head for a first species of a second embodiment, Fig. 3B being an enlarged side elevation view of a portion of the head shown in Fig. 3A;

Fig. 4 is a cutaway, side elevation, semi-schematic representation of a second species
5 of the second embodiment of the invention;

Fig. 5A is a cutaway, side elevation, semi-schematic representation of a third species of the second embodiment of the invention, Fig. 5B being an enlarged, side elevation view of a portion of the species shown in Fig. 5A;

Fig. 6 is a cutaway, side elevation, semi-schematic representation of a first species for
10 a third embodiment of the invention;

Fig. 7 is a cutaway, side elevation, semi-schematic representation of a second species for the third embodiment of the invention;

Figs. 8 and 9 are cutaway, side elevation, semi-schematic representations of a third and fourth species of the third embodiment of the invention;

15 Figs. 10A and 10B are graphic representations illustrating the back scattering effect for a narrow and a wide beam respectively;

Fig. 11 is a graphic representation of the relationship between a coefficient for amplification of irradiance in a scattering medium and beam diameter for three mediums having different diffuse reflecting characteristics; and

20 Fig. 12 is a cutaway, side elevation, semi-schematic representation of a fourth embodiment of the invention.

Detailed Description

Referring first to Fig. 1, a laser head 10 is shown which contains a plurality of laser
25 diode bars 11, each of which includes a plurality of emitters 11A and is mounted in a groove 13 formed in a block 12. Block 12 may be formed of one or more materials having good thermal conduction properties, and may be fabricated in a number of ways, all of which are within the contemplation of this invention. In particular, block 12 may be formed of a single material which, in addition to having good thermal conduction properties, is also an electrical
30 insulator, with the side walls of grooves 13 being coated or plated with an electrically conducting material and the diode bars soldered in the grooves, an electrical circuit being

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formed between adjacent grooves so that current may flow through the diodes without being shorted through block 12. Alternatively, the portion of block 12 between grooves 13 may be fabricated of electrically conductive mounts which are secured in a suitable way to a thermally conducting and electrically insulating substrate, the conducting mounts providing an electrical path through the diodes and the insulating substrate preventing shorts. Other techniques for providing an electrical path through the diodes to permit selective energization thereof, while not provided a short circuit path through block 12 may also be employed.

Block 12 serves as a heat sink for diode bars 11 and a variety of techniques may be utilized to remove heat from block 12. These include providing one or more channels through block 12 and flowing a fluid, which is generally water but may be some other liquid or gas, through the channel to remove heat from block 12. Alternatively, one or more thermo-electric components 14, for example Peltier elements, may be attached to block 12 and utilized to remove heat therefrom.

A transparent element 15 having a high reflectivity mask 16 attached thereto is mounted to the bottom of block 12, with mask 16 preferably being between block 12 and element 15. For a preferred embodiment where head 10 is being used for dermatological treatment, the scattering media 18 being the skin of a patient, the transparent element is preferably formed of sapphire or some other material having a good index match with skin, and is preferably either a sapphire coating which is for example 1 to 2 microns thick, or a sapphire plate or wafer which is for example 1 to 2 mm thick. If component 15 is a plate or wafer, then mask 16 may be a coating of a highly reflective material such as Ag, Cu, Au or a multilayer dielectric coating which is formed using an appropriate coating technology known in the art, such as lithography, on the plate/wafer 15. Openings 20 (Fig. 2A) are formed in the coating 16 under each of the diode bar emitter 11A, the openings 20 being only large enough to permit light from the diode bars to pass unobstructed therethrough. Keeping slits or openings 20 in reflective layer or mask 16 as small as possible is desirable in that it maximizes the reflectivity of the mask and thus, as will be discussed later, optimizes retroreflection of scattered energy from skin or other media 18. For reasons which will be discussed in greater detail later, reflective layer 16 should have a larger footprint than block 12 to further enhance the reflection back into the media 18 of scattered light or energy emitted therefrom. Since for the illustrative embodiment, mask 16 is supported on transparent plate

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or wafer 15, this component also has a larger profile. Alternatively, mask 16 may be a thin plate or wafer having slits 20 formed therein, and transparent component 15 may be a layer of for example sapphire having a thickness in the 1 to 2 micron range which is coated thereon. In this case, the coating need not extend beyond the dimensions of block 12; however, it is preferable that this coating extend for the full dimensions of mask 16 to provide a good optical index match for retroreflected light.

Finally, the apparatus of Fig. 1 includes a box 23 connected to head 10 by suitable electrical lines and, where appropriate, plumbing lines (for cooling water) 24. Box 23 may contain appropriate power supplies for diodes bars 11, control circuitry, fluid pumps where fluid cooling is utilized and other appropriate components. The specific components contained in box 23 do not form part of the present invention.

The apparatus of Fig. 1 has several advantageous features over the prior art. First, where the medium 18 is the skin of a patient undergoing a dermatological procedure, such as for example the removal of a tattoo, a port wine stain, blood vessel, or other vascular lesion, or hair removal, it is desirable to cool the epidermis, the surface layer of the skin, to prevent thermal damage thereto during the procedure. In the prior art, a cooling mechanism has been provided for the epidermis in particular, and for the surface area of a patient's skin in general, which cooling mechanism is separate and independent from the cooling mechanism utilized to sink heat from diode bars 11. These separate cooling mechanisms add to the size, weight, complexity and cost of the system in general, and of the delivery head 10 in particular. The embodiment of Fig. 1 overcomes these problems by having at most a few millimeters of material between the block 12, which is cooled by thermoelectric components 14, by a flowing fluid, and/or by other suitable means, and the patient's skin. Further, the sapphire typically used for transparent component 15 has good thermal transfer properties so that heat from the patient's skin may easily flow to cooled block 12, and this block may serve as a heat sink for both diode bars 11 and the epidermis of a patient's skin or other surface area of a media 18 to which light energy is being applied. This arrangement is more compact, simpler and less expensive than prior art heads performing the same function.

Further, as illustrated in the Figure, light energy emitted from a diode bar 11 in the form of rays 26 is scattered in media 18, for example in a patient's skin, and at least some of this energy, perhaps 70 percent, depending on the pigmentation of the patient's skin, is

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reflected back and exits the patient's skin at some angle. Substantially all of this light impinges on reflecting surface or mask 16, and, since this mask has a reflectivity approaching 100 percent, substantially all of this light energy is retroreflected back into the skin. This retroreflection results in a roughly 300 percent increase in the light energy or fluence reaching a target at a selected depth in the patient's skin for a given fluence emitted from diode bars 11. This means that either the same therapeutic results can be achieved using less diode bars 11 or lower energy diode bars 11 or that higher energy, and therefore more effective treatment, can be achieved using the same number and power of diode bars. More effective results can thus be achieved for a given size, cost and complexity of the diode laser head.

Further, as illustrated in Fig. 10B, light energy entering scattering medium 18 over an aperture of size D will, because of beam divergence and scattering, exit the medium over an aperture $D + d$, where d is a back-scatter aperture increment and is substantially constant for a given beam wavelength and medium, regardless of the input aperture D . This is illustrated by Figs. 10A and 10B, where d is substantially the same for a thin beam which substantially enters the medium 18 at a single point and for a wide beam having an aperture D . Thus, as the aperture size D increases, d becomes a smaller percentage of the reflection aperture $D + d$. For a generally circular aperture, D and $D + d$ are diameters, while for a generally rectangular aperture, these values may be considered to be the length of the smaller side of the rectangle.

The reflection by reflective mask 16 can increase the amount of energy reaching a desired target area by several times. This increase in effective usage of light energy can be quantitatively described by the increase in illumination inside scattering medium 18, this increase being the ratio (f) between the illumination at an arbitrary target point inside the scattering medium when the reflected light is returned back to the medium (I_R) and when it is not (I_O) (i.e., $f = I_R/I_O$). The value of f depends on the reflectance coefficient R of the scattering medium 18 and the coefficient of reflection of the reflecting mask 16 (r) which returns the scattered light back into the medium (i.e., $f = 1/1 - Rr$). However, this known dependence does not take into account the influence of beam aperture D ; since the beam aperture increases by d as a result of scattering, amplification coefficient f has a strong dependence on the aperture D of the incident beam. In particular, in accordance with the

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teachings of this invention, it has been determined that when beam aperture is taken into

$$f = \frac{1}{1 - Rr \left(\frac{D/d}{1 + D/d} \right)^2} \quad (1)$$

account, the amplification coefficient f can be approximated by the following equation:

Using equation 1 for a given medium, a given reflector, and a desired illumination amplification, a minimum beam aperture (D_{\min}) can be determined. D_{\min} is generally given by:

$$D_{\min} = d \cdot \frac{1}{\frac{\sqrt{f \cdot R \cdot r}}{f - 1} - 1} \quad (2)$$

5

$$D_{\min} = d \cdot \frac{1}{\sqrt{2 \cdot R \cdot r} - 1} \quad (3)$$

For $f=2$, this minimum reduces to

With light skin as a reflecting medium, and an incident beam in the red region of the spectrum, the values in the above equation would be $R \approx 0.7$ and $d \approx 3$ mm. Assuming a reflector with $r \approx 0.95$ would then result in a $D_{\min} = 19.5$ mm. This suggests that for most

10 applications in laser dermatology, the beam diameter or other appropriate dimension (D) should be greater than 20 mm in order for retroreflection to provide desired illumination amplification. This is illustrated in Fig. 11 where (f) is shown as a function of the ratio D/d for three reflection environments, with r being 0.95 in each instance, and with R equaling 0.2, 0.5 and 0.8, respectively. It is seen that, particularly for the highly scattering medium having

15 $R=0.8$, f continues to increase with increasing input aperture size and may, with retroreflection, provide up to 3.8 times the intensity achieved without retroreflection.

Assuming d is equal to 3 mm, an input aperture of 20 mm would result in well over two times the illumination at the target than if retroreflection were not utilized, and a smaller aperture, for example $D=15$ mm, would still provide significant amplification. Thus, while each

20 individual diode bar 11 produces a beam having a dimension in the micron range, head 10 can

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be designed to provide a beam having a dimension D which is sufficient to provide a desired illumination amplification. The reflecting surface 16 is preferably made large enough so as to fully cover the reflection aperture which consists of $D + d$, but may require little or no extension beyond the end of block 12 where D is large relative to d .

5 The embodiment shown in Fig. 1 thus provides at least three significant advantages over prior art laser diode heads. First, it provides a very efficient mechanism for cooling both the laser diodes and the surface of medium 18 by use of the same cooling mechanism. Second, it provides a simple and effective mechanism for retroreflecting light scattered from medium 18 over the entire scattering aperture from such medium; and third it provides a beam
10 aperture which is large enough for efficient illumination amplification as a result of retroreflection while using radiation sources, for example laser diode bars, which individually provide small beam apertures in the micron range.

 Fig. 2B illustrates an alternative embodiment of the invention which may be useful in some applications. The embodiment of Fig. 2B differs from that of Fig. 2A in that
15 transparent layer 15 has been replaced by a cylindrical lens 31 mounted under each of the laser diode bars 11. Cylindrical lenses 31 can be supported to the array in ways known in the art including a support bracket or other support structure, either mounted to or forming part of block 12 at opposite ends of each cylindrical lens 31. Block 12 also extends somewhat below the bottom of diode bars 11 so as to supply structural support for lenses 31 and to
20 permit block 12 to contact the upper surface of medium 18 when slight pressure is applied to block 12 so that the block may still function to cool the surface of the medium. A reflective coating 16 is formed on the bottom wall of block 12 in all areas thereof except the areas directly under diode bar emitters 11A, the reflective coating otherwise extending substantially around the entire wall of the recess in which lens 31 is positioned. Depending on its diameter,
25 a lens 31 may function to collimate beam 26 emanating from the corresponding diode bar 11 into parallel rays, as opposed to diverging rays as shown in Fig. 2A, or to converge such beams toward a focal point which is preferably at the target depth. Such a collimating or converging of beam 26 reduces the ill effects of scattering on the beam, but does not eliminate such scattering or significantly reduce the need for reflective surface 16.

30 Fig. 3 shows an embodiment which differs from that of Fig. 1 in that higher fluence is required than is provided by the diode bars alone, even with retroreflection. Therefore,

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energy emitted from transparent layer 15 is applied to a standard concentrator 34A, which may be a hollow truncated cone or prism, but is preferably a block or slab of material having a good index match and good heat transfer properties to the medium 18, for example sapphire when the medium is human skin. Concentrator 34A sacrifices aperture size in order to achieve higher fluence in a manner known in the art. However, the aperture size is maintained sufficient to conform to the requirements specified in equation (2) above in order to maintain the energy amplification effects of retroreflection.

The embodiment of Fig. 3 also deals with a second problem in that scattered light is emitted from the skin at a variety of angles and is returned to the skin generally at the same angle received. This results in a higher concentration of optical energy at the surface of the skin where all beams are received and lower energy at depth, where the desired target is generally located, sharply angled beams only appearing at the surface. Since energy concentrated at the skin surface serves no useful therapeutic purpose and can cause thermal damage or discomfort if not adequately cooled, it is desirable to reduce or eliminate such sharply angled reflected beams, while not interfering with beams reflected at angles substantially perpendicular to the medium surface and returned to the skin at these angles. This objective is accomplished for the embodiment of Fig. 3 by providing a coating 32 on the side walls of concentrator 34A, which coating has angle-dependent reflection characteristics and may have significantly lower reflectivity than reflective surface 16. This means that the sharply angled beams impinging on surface 32 are attenuated or eliminated, thereby reducing the beams entering medium 18 at a sharp angle, these beams being only harmful and producing no useful therapeutic effect.

While the embodiment of Fig. 3 has the advantages discussed above, it also has two potential disadvantages. First, the aperture for receiving reflected radiation is smaller than the aperture (i.e., $D + d$) of reflected radiation, so that this embodiment does not collect all reflected radiation and retroreflect it to medium 18. This results in a slight decrease in the intensity amplification ratio (f) for this embodiment; however, this disadvantage is mitigated by the fact that much of the energy lost for this embodiment is energy at angles which, even if retroreflected, only contribute to heating the surface of medium 18 and do not to have a therapeutic effect or do other useful work at a target area located at a selected depth in the

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medium. D being larger than (d) also minimizes this loss. If desired, reflective extensions could also be provided for this embodiment to retroreflect all reflected energy.

The second disadvantage is that, depending on the thickness of concentrator 34A, cooled block 12 may not be effective for cooling the surface of medium 18. In particular, the time (t) it takes to remove heat from a slab of material having one side in good thermal contact with the surface to be cooled, an opposite side in good thermal contact with the cooling

$$t \sim l^2 / \alpha \quad (4)$$

medium, in this case the block 12, and a distance or thickness (l) therebetween is given by: where α is the dielectric slab temperature conductivity coefficient. Where energy is being applied to the slab as successive laser pulses spaced by a time t_p , the slab thickness l for

$$l < \sqrt{\alpha \cdot t_p} \quad (5)$$

cooling to be affected is generally given by:

Where the dielectric layer through which optical energy is transmitted and through which it is desired to perform cooling is formed of sapphire having a maximum $\alpha = 15 \cdot 10^{-6} \text{ m}^2/\text{s}$, and for a typical interval between pulses of 0.25 s, this would result in the combined thickness for transparent layer 15 and concentrator 34A of less than 1.9 mm. Therefore, block 12 being utilized to cool both diode bars 11 and the surface of medium 18 would normally not be feasible when a concentrator 34A is utilized and, if cooling is required, it would normally be achieved by providing a separate cooling mechanism, for example one or more thermoelectric cooling elements 36, in contact with concentrator 34A, and preferably near the lower surface thereof. While only a single such cooling element is shown in Fig. 3, typically four or more such elements would be provided, spaced substantially evenly around the periphery of concentrator 34A, to provide uniform cooling thereof.

Figs. 4 and 5 illustrate two additional embodiments of the invention which differ from that shown in Fig. 3 only in that, in Fig. 4, slab 34B is an expander rather than a concentrator, while in Fig. 5, slab 34C has parallel walls so as to not function either as a concentrator or an expander. Slabs 34A, 34B and 34C therefore permit a single block 12 with diode bars 11, transparent layer 15 and reflective layer 16 to be used to achieve a variety of programmable

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fluence levels. The embodiment of Fig. 4 is advantageous in that it permits more of the scattered light emitted from the surface of medium 18 to be collected and recycled than the other embodiments, with the embodiment of Fig. 5 having intermediate scattered light collecting capabilities. All three embodiments can have angle-dependent reflecting side walls 32 so as to reduce or substantially eliminate light being emitted at sharp angles. While the reduced reflection of surfaces 32 may be uniform, it is preferable that the reflectance from these surfaces be angle-dependent so that light impinging on these surfaces at sharper angles are more heavily attenuated, while light impinging on these surfaces at lesser angles, and therefore light which is more nearly emitted from the surface in a perpendicular direction, are attenuated much less, or in other words are more fully reflected. Further, reflecting surface 16 for all embodiments can also be angle-dependent, reflecting more strongly for light coming in at substantially perpendicular angles than for light coming in at sharper angles. While this may be achieved with a single layer coating, it is preferably achieved with a multilayer coating.

Figs. 6-8 illustrate various species of still another embodiment of the invention wherein block 12 is replaced with a block 42 having a recess 44 formed therein. Grooves 13 are formed in a selected pattern around the perimeter of recess 44. In particular, referring to Fig. 6, the block 42A has a semi-cylindrical recess 44A formed therein with grooves 13 having diode bars 11 mounted therein being arranged in a semi-circular pattern around the periphery of recess 44A, each groove 13 and diode bar 11 therein being substantially perpendicular to the circumference of recess 44A (i.e., substantially parallel to a radii) at the point on the circumference where they are located. Part of the media 18 adjacent recess 44A is brought up therein and into contact with transparent surface 15 formed on the inside of the recess. Media may be brought into recess 44A either by pressing block 42A against a relatively soft media 18, for example skin in certain areas, to force the skin into the recess, or a source of vacuum may be provided, either adjacent the bars near the middle of the recess or between such bars, to pull the skin into the recess. Other techniques for forcing skin or other media 18 into the recess 44A may also be employed, either in addition to or instead of one or more of the two techniques mentioned above. Finally, the lower portion of block 42A outside of recess 44A has an angle-dependent reflective coating 32 formed thereon, this surface reflecting some light back into the skin in an area where it may be scattered to recess 44A.

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For the embodiment of Fig. 6, the target area for the light energy would be at roughly the foci of the diode bars, which would generally be a point near the bottom center of recess 44A. Any light reflected by the skin prior to reaching such a target area would typically be reflected back into the recess and ultimately returned to the target resulting in a very high illumination increase ratio (f) for this embodiment.

Fig. 7 illustrates an embodiment which differs from that of Fig. 6 in that the recess 44A in block 42A, instead of merely having a thin transparent layer 15, has a transparent block or lens 40 positioned therein with a narrow rectangular recess 48 formed in cylindrical lens 40. Grooves 13 and the diode bars 11 mounted therein are at a slightly greater angle so as to have a focus near the upper middle of recess 48. The embodiment of Fig. 7 is particularly adapted for hair removal applications where a fold of skin having a single hair follicle in the plane of the Figure (there may be several hair follicles in the recess 48 along the length of the recess) is in recess 48 at a given time. Vacuum would normally be required to draw such a fold of skin into recess 48. As for the embodiment of Fig. 6, this embodiment results in a high concentration of light, including light reflected from reflecting surface 16 reaching the target point in recess 48. This effect is further enhanced by providing a highly reflective coating 49 on the bottom surface of cylindrical lens 40 which prevents light from exiting the lens into medium 18. Thus, substantially 100 percent of the light produced by diode bars 11 for this embodiment of the invention is applied to the target area, with virtually no energy being lost to scattering.

Fig. 8 is similar to Fig. 6 except that recess 44B in block 42B has a rectangular cross-section rather than a semi-circular cross-section, and grooves 13 are perpendicular to the walls of recess 44B at the points where they are located. While this embodiment does not result in a focusing of the light at a single point as for the embodiments of Figs. 6 and 7, it does result in a high concentration of light energy in recess 44B which is applied to medium moved into the recess by pressure, vacuum, or other suitable means.

The embodiment of Fig. 9 is similar to that of Fig. 1 except that rather than there being extended portions for layers 15 and 16, there are flexible extensions 52 on each end of the block, which extensions have an angle-dependent reflective coating 32 formed thereon. Vacuum may be used to draw part of medium 18 into the area under block 12 and extensions 52 to provide enhanced radiation of a target area in this region or thereunder. The side

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sections 52 with angle-dependent reflective coating are more effective in directing light energy in the (d) region (Fig. 10B) into the target area than are the flanges of Fig. 1.

While not specifically mentioned above, the embodiments of Figs. 6-9 can also utilize the cooling technique of Fig. 1 wherein block 12 and/or block 42 is utilized both to cool diode bars 11 and to cool the surface of the skin or other media 18. The embodiment of Fig. 7 is not as effective for achieving this objective as some of the other embodiments.

While for the embodiments described above, diode bars have been mounted in block 12 of head 10, in some applications other light emitters, for example filament lamps such as halogen lamps, could be suitably mounted in block 12 in place of the diode bars. Many of the advantages of this invention could also be achieved if a light pipe receiving light from a laser or other light emitting source is substituted for each diode bar 11 for the various embodiments. For example, Fig. 12 shows a head 10' which differs from that shown in Fig. 1 in that light from a laser or other light energy emitter of suitable power and wavelength is passed through a light pipe in lines 24 to a network of light pipes 60 in block 12, there being a plurality of light pipes 60 behind each light pipe shown to provide substantially the same light emission pattern as for the plurality of emitters 11A of each diode bar 11. The minimum aperture size D to achieve a selected amplification (f) from retroreflection is also applicable to substantially any laser or other light energy emitting head used on a scattering medium, including those shown in various prior patents and applications including 5,595,568; 5,735,844; 5,824,023, and application serial No. 09/078055, Fig. 4 of which, for example, shows a head which may be used in practicing the teachings of this invention, but which differs from Fig. 12 in that the light pipes are angled to focus the light energy. Where light pipes are utilized, transparent layer or element may not be required, and reflective coating 16 can be applied directly to the bottom surface of block 12, with openings in the coating being provided under each light pipe.

Further, transparent layer 15 is preferably spaced by at least several micron, for example 50-100 microns, from the diode bars to assure against shorting of the laser bars, and this space may be filled with air or other gas, or with a liquid or solid insulating material which is transparent at least in the areas under the openings or slits in the reflective layer 16. For this embodiment, the spacing may be such that cooling of the medium from block 12 is no longer possible.

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An invention has thus been disclosed, including a number of embodiments and various species of each embodiment, which provides a simpler cooling mechanism for certain embodiments for the surface of a medium undergoing a laser or other optical energy procedure and which also provides more optimum, and in some cases substantially optimum, use of light energy produced by diode laser bars, or other optical energy source, even when the light is being delivered to a highly scattering medium, by designing the device to provide an adequate input aperture and suitable mechanisms for retroreflecting such light. Further, while a number of embodiments and species thereof have been disclosed, it is apparent that these are being provided for purposes of illustration only and that other similar or equivalent mechanisms might also be employed. Thus, while the invention has been particularly shown and described above with reference to preferred embodiments and species, the foregoing and other changes in form and detail may be made therein by one skilled in the art without departing from the spirit and scope of the invention, which is to be defined only by the appended claims.

What is claimed is:

CLAIMS

1. A head for applying light energy to a selected depth in a scattering medium having an outer layer in physical and thermal contact with said head including:
 - a thermally conductive mount having an energy emitting surface;
 - at least one optical energy emitting element mounted in said mount adjacent said energy emitting surface, each said element being in thermal contact with said mount and oriented to direct light energy through said surface;
 - a thin, transparent, thermally conductive layer over said surface and in thermal contact therewith, said layer being in contact with said outer layer of the medium when the head is applying light energy thereto; and
 - a cooling mechanism for said mount, permitting said mount to sink heat from both said at least one element and said outer layer of the medium.
2. A head as claimed in claim 1, including a reflecting layer on said thermally conductive layer, said reflecting layer having an opening formed therein under each said at least one element through which light energy may be applied to said medium.
3. A head as claimed in claim 2, wherein said reflecting layer has a larger area than the area of said mount.
4. A head as claimed in claim 3, wherein the area of said reflecting layer is at least substantially as large as an aperture of reflection for scattered light energy from said medium.
5. A head as claimed in claim 2, wherein light energy is applied to said medium through an aperture, wherein there is a desired amplification coefficient f as a result of retroreflection from said reflecting layer, wherein the medium and the reflecting layer have reflecting coefficients R and r respectively, and wherein the minimum value D_{\min} for a dimension D of the aperture is

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$$D_{\min} = d \cdot \frac{1}{\frac{\sqrt{f \cdot R \cdot r}}{f - 1} - 1}$$

6. A head as claimed in claim 1, wherein said mount has a depression formed therein, said energy emitting surface being the surface of said depression, each of said element being mounted to emit light energy substantially perpendicular to the depression surface at the point thereon where the element is mounted, said medium being forcible into said depression and into contact with the surface thereof.

7. A head as claimed in claim 6, wherein said depression is substantially hemispherical in shape.

8. A head as claimed in claim 6, wherein said depression is substantially rectangular in shape.

9. A head as claimed in claim 1, wherein said thermally conductive layer is a coating formed on said light emitting surface.

10. A head as claimed in claim 1 wherein each said element is a diode laser bar.

11. A head for applying light energy to a selected depth in a scattering medium including:
a block having an energy emitting surface;
at least one source of light energy, each said source directing light energy through a selected portion of said surface; and

a layer between said energy emitting surface and said medium and in contact with said medium when the head is applying light energy thereto, said layer including at least a reflective layer covering all portions of said surface except each said selected portion through which light energy is directed, said reflecting layer retroreflecting light energy scattered from said medium.

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12. A head as claimed in claim 11 wherein each said source of light energy includes a light guide extending at least part way through said structure from said surface and optically connected to receive light energy from a light emitting component.

13. A head as claimed in claim 12 wherein said light emitting component is one of a laser, a flash lamp and a filament lamp.

14. A head as claimed in claim 12 wherein said layer is a reflective layer formed on said surface, which reflective layer has an opening formed therein under each said light guide.

15. A head as claimed in claim 11, where the area of said reflecting layer is at least substantially as large as an aperture of reflection for scattered light energy from said medium.

16. A head as claimed in claim 11, wherein light energy is applied to said medium through an aperture, wherein there is a desired amplification coefficient f as a result of retroreflection from said reflecting layer, wherein the medium and the reflecting layer have reflecting coefficients R and r respectively, and wherein the minimum value D_{\min} for a dimension D of the aperture is

$$D_{\min} = d \cdot \frac{1}{\frac{\sqrt{f \cdot R \cdot r}}{f - 1} - 1}$$

17. A head as claimed in claim 11 wherein each said source includes a light energy emitter mounted in said block so as to emit its light energy through the corresponding selected portion of said surface.

18. A head as claimed in claim 17 wherein each said emitter is mounted adjacent to, but spaced from, said surface, and wherein said layer includes a transparent layer over said surface with said reflective layer being on at least one side of said transparent layer.

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19. A head as claimed in claim 17, wherein said reflecting layer has a larger area than the area of said surface.

20. A head as claimed in claim 17, wherein said transparent layer is a waveguide of selected shape.

21. A head as claimed in claim 20 including an angle dependent reflecting layer on selected walls of said waveguide to attenuate sharply angled light energy entering the waveguide.

22. A head as claimed in claim 20, wherein said selected shape is a truncated pyramid, one of a larger end and a shorter end of a pyramid being adjacent said mount.

23. A head as claimed in claim 17, wherein said transparent layer is a coating formed on said light emitting surface.

24. A head as claimed in claim 17 wherein said emitter is one of a diode laser bar and a filament lamp.

25. A head as claimed in claim 11, wherein said block has a depression formed therein, said energy emitting surface being the surface of said depression, each said source of light energy directing light energy substantially perpendicular to the depression surface at the corresponding selected portion of the surface, said medium being forcible into said depression and into contact with the surface thereof.

26. A head as claimed in claim 11 wherein said block has a depression formed therein, said energy emitting surface being the surface of the depression, a transparent block filling said depression and a narrow recess formed in said transparent block, said at least one source directing light energy to said surface so as to focus light at a point in said recess.

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27. A head for applying light energy to a selected depth in a scattering medium including:
a mount having an energy emitting surface;
at least one energy emitting element mounted to apply light energy to said medium through an aperture; and
a reflecting layer mounted to retroreflect light energy back-scattered from said medium;
the aperture having a minimum value D_{\min} for a dimension D of the aperture which is:

$$D_{\min} = d \cdot \frac{1}{\frac{\sqrt{f \cdot R \cdot r}}{f-1} - 1}$$

28. A head as claimed in claim 27 wherein said aperture is substantially circular, and wherein D is the diameter of the aperture.
29. A head as claimed in claim 27 wherein said aperture is substantially rectangular and D is the length of a short side of said aperture.

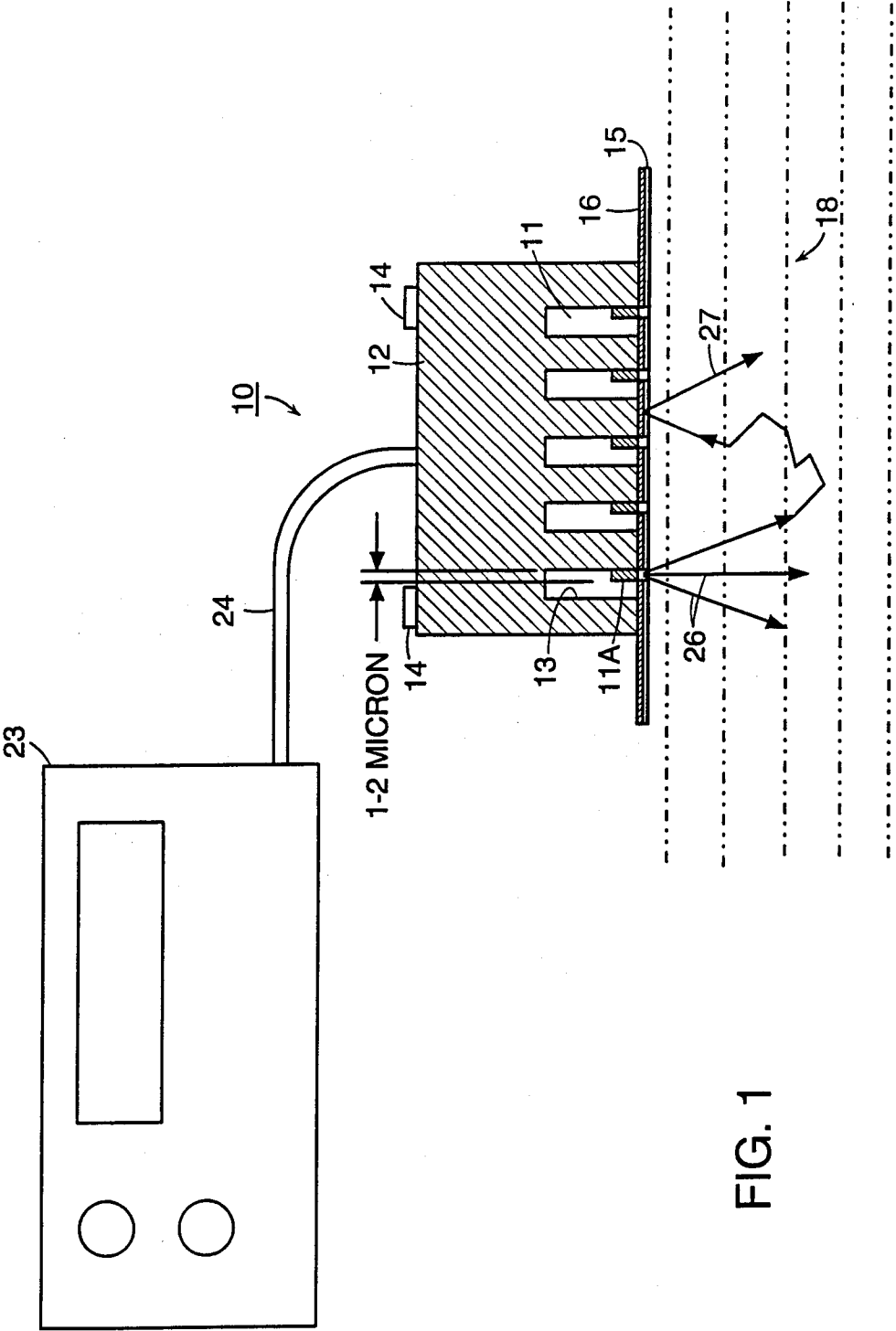


FIG. 1

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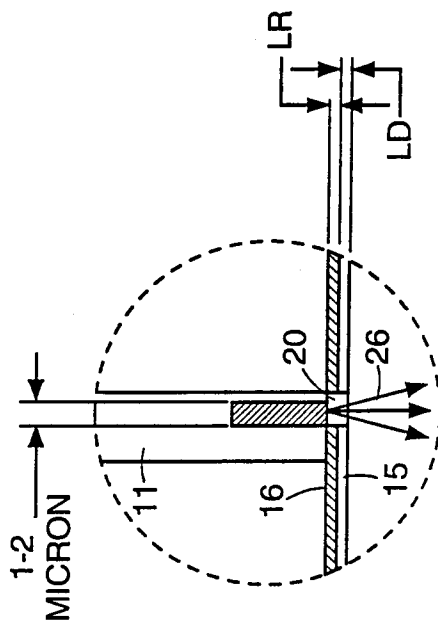


FIG. 2A

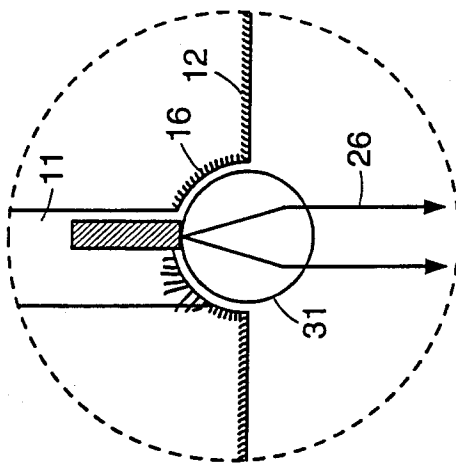


FIG. 2B

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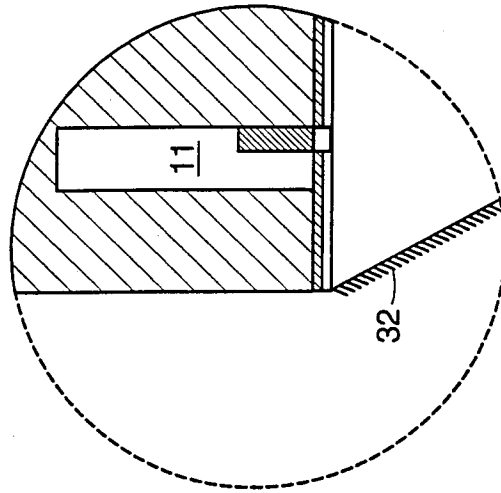


FIG. 3B

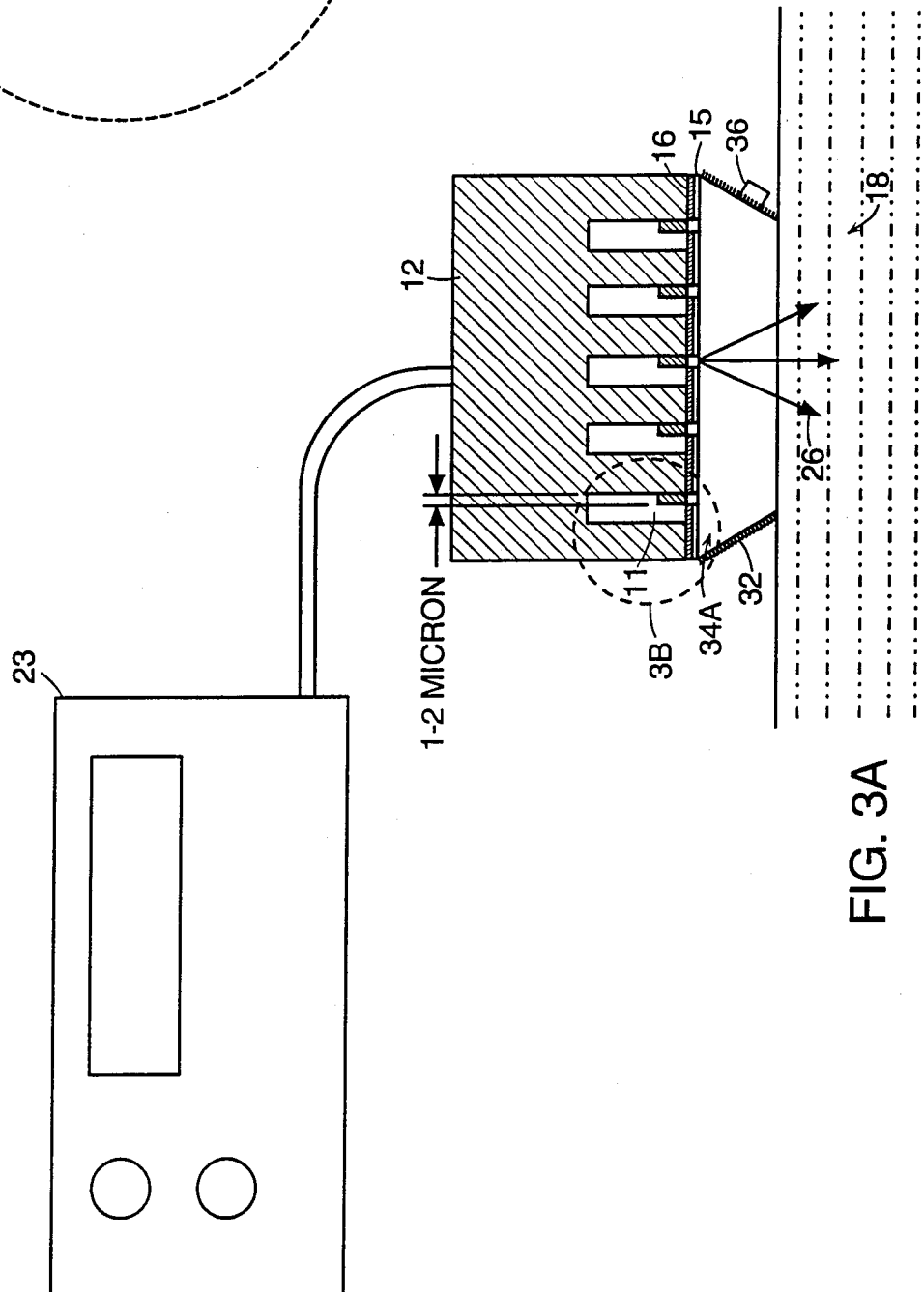
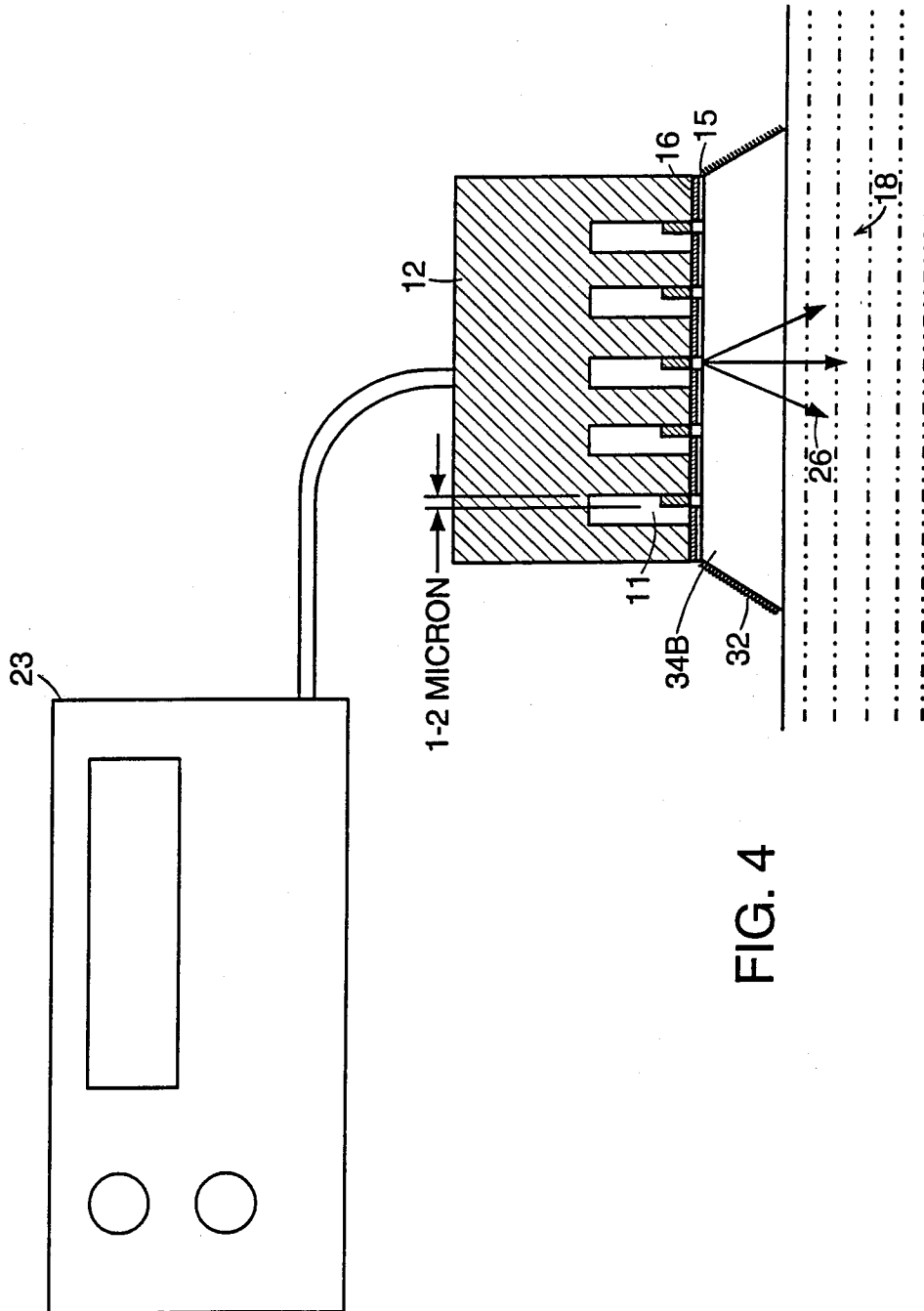


FIG. 3A

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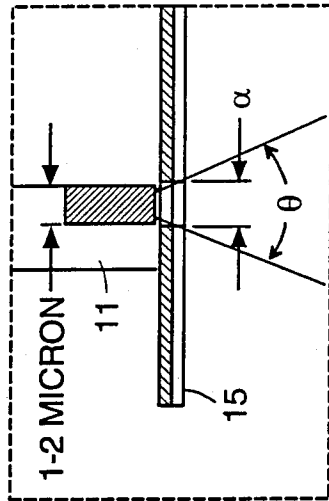


FIG. 5B

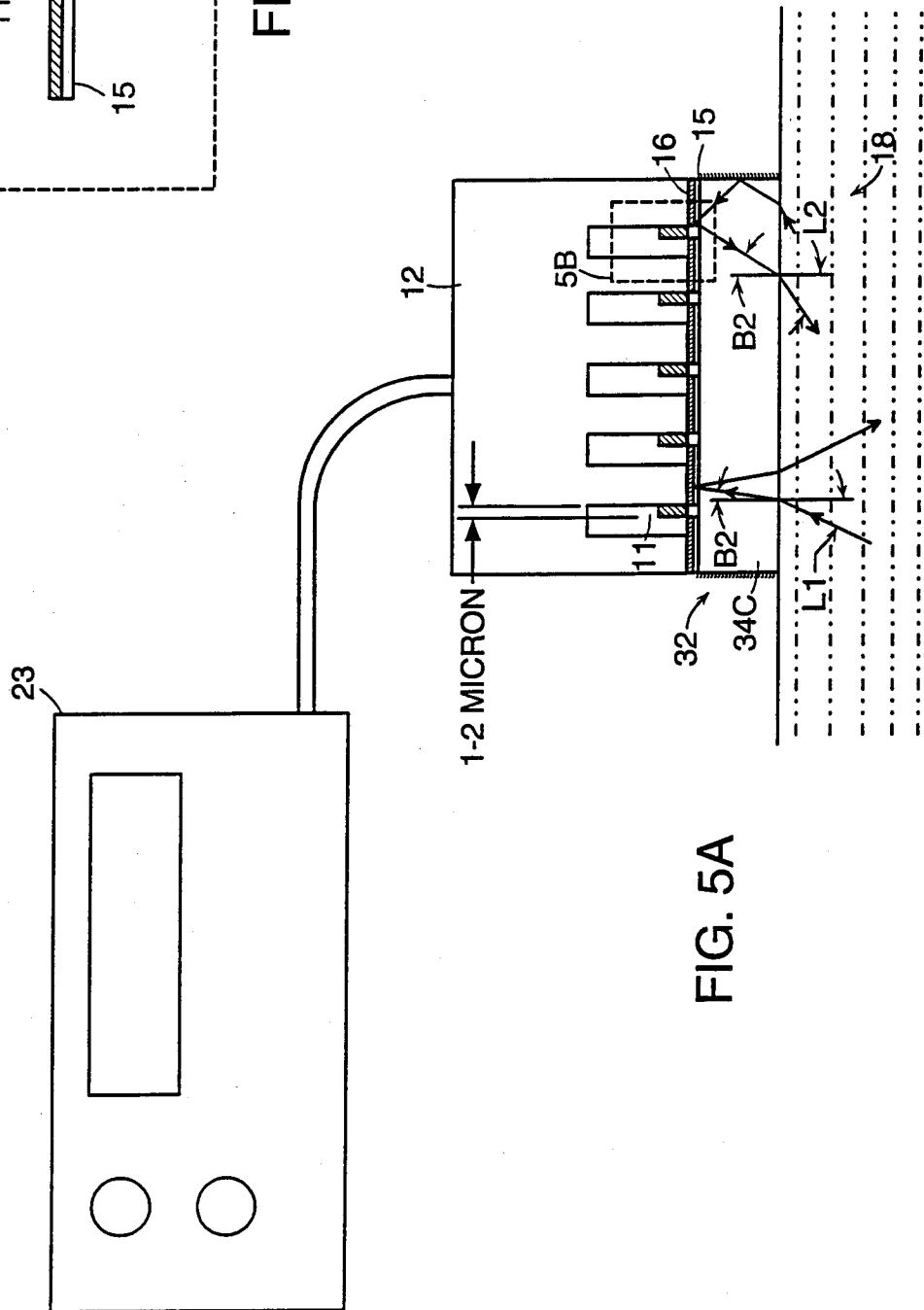


FIG. 5A

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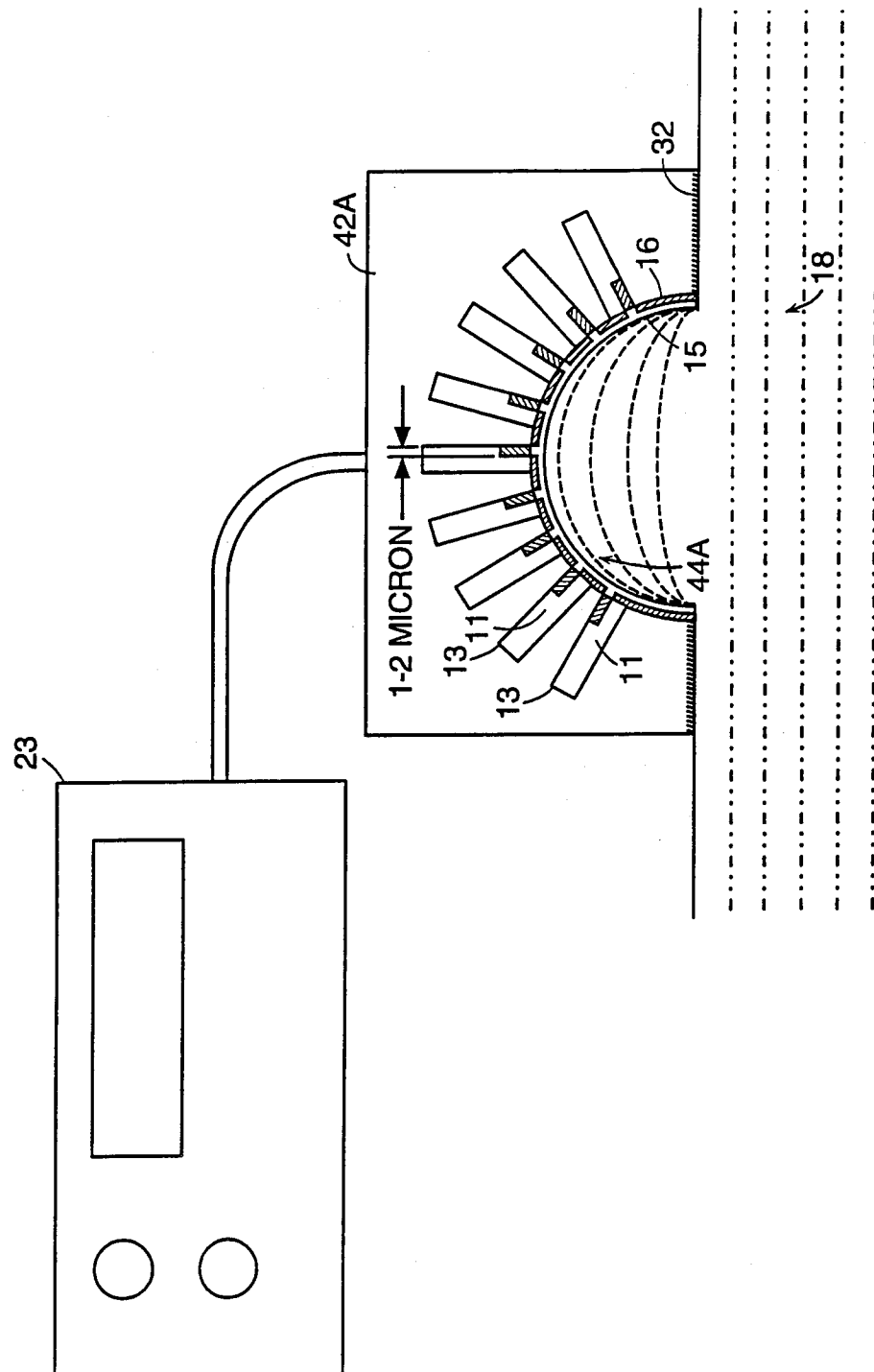


FIG. 6

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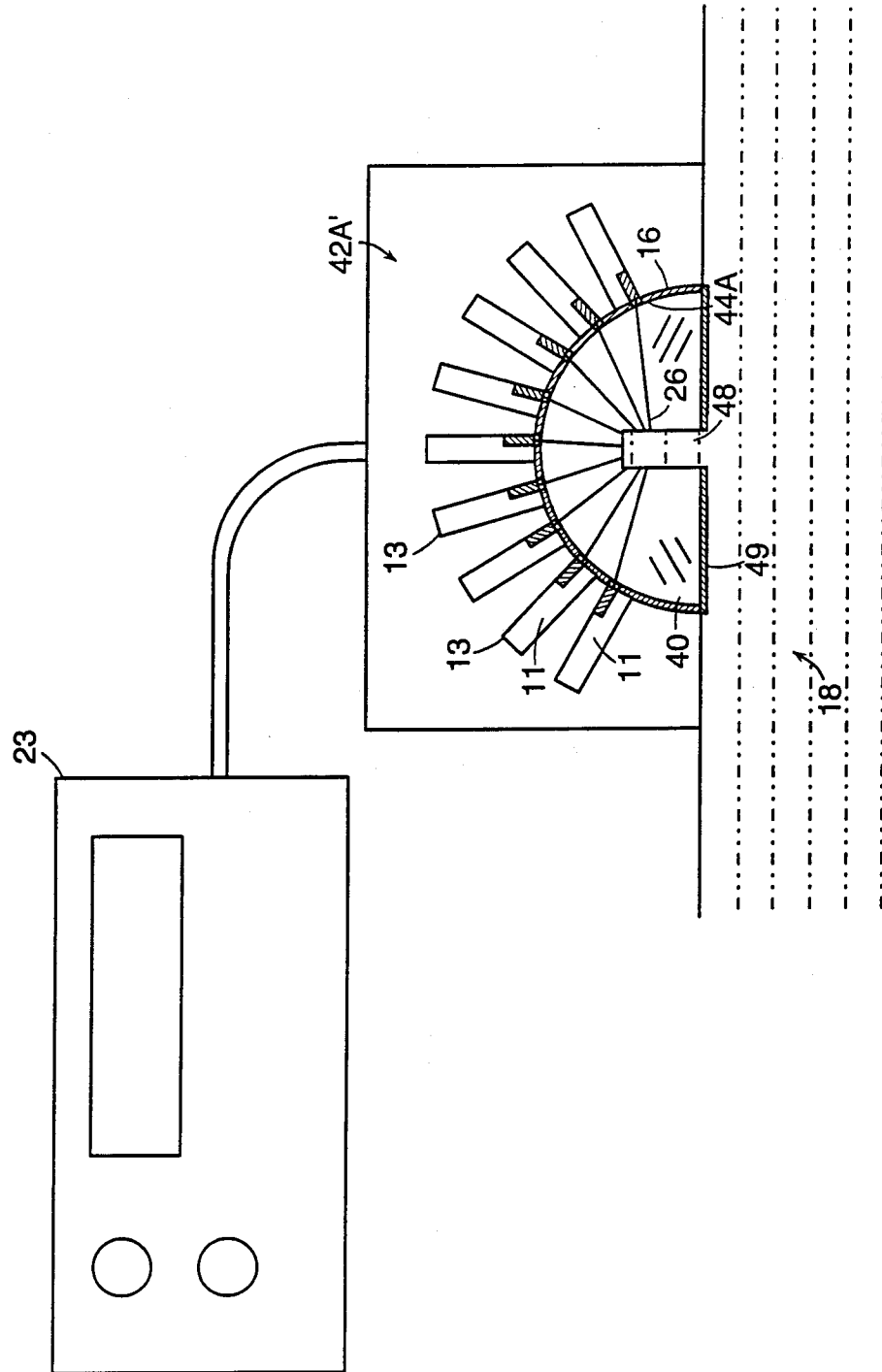


FIG. 7

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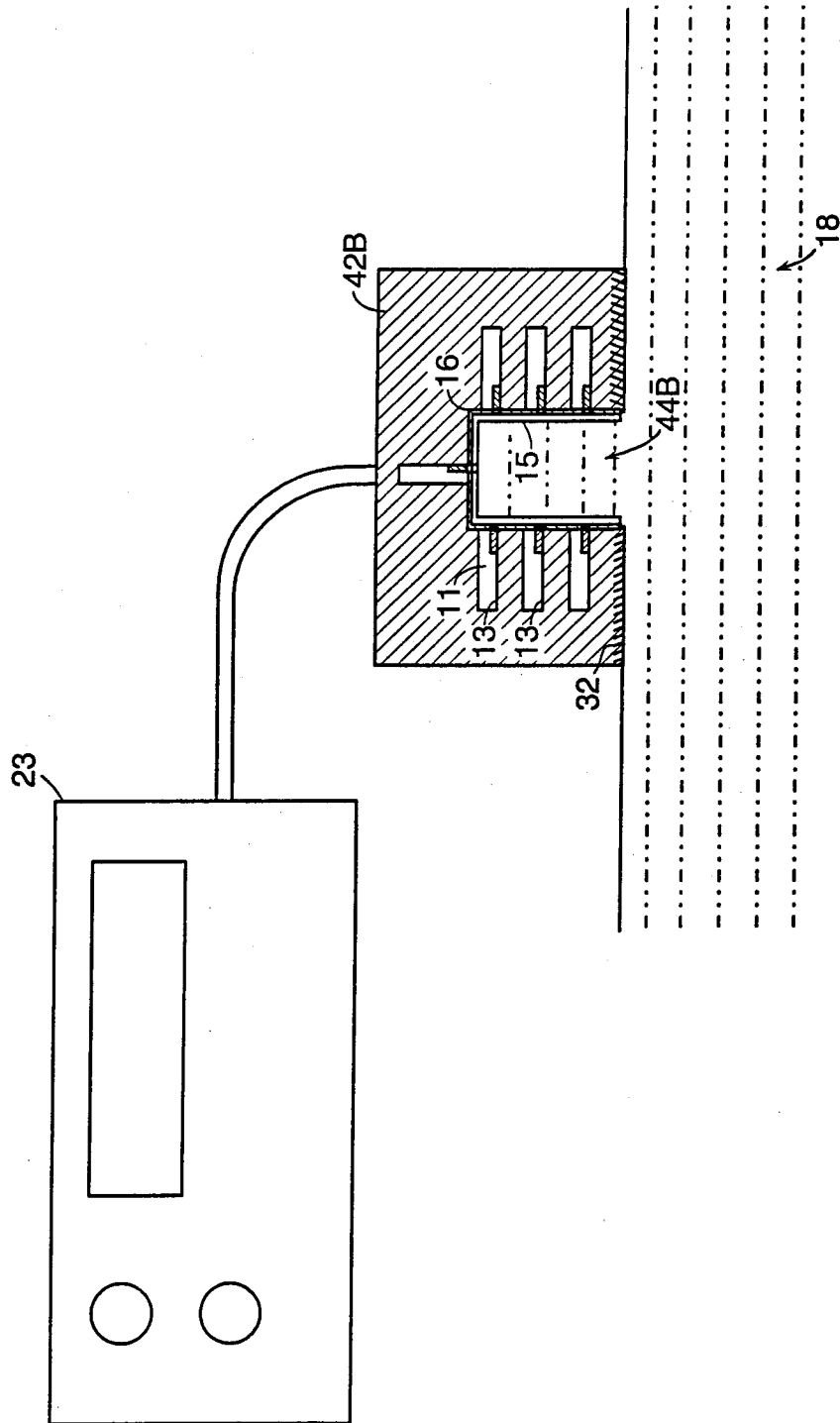
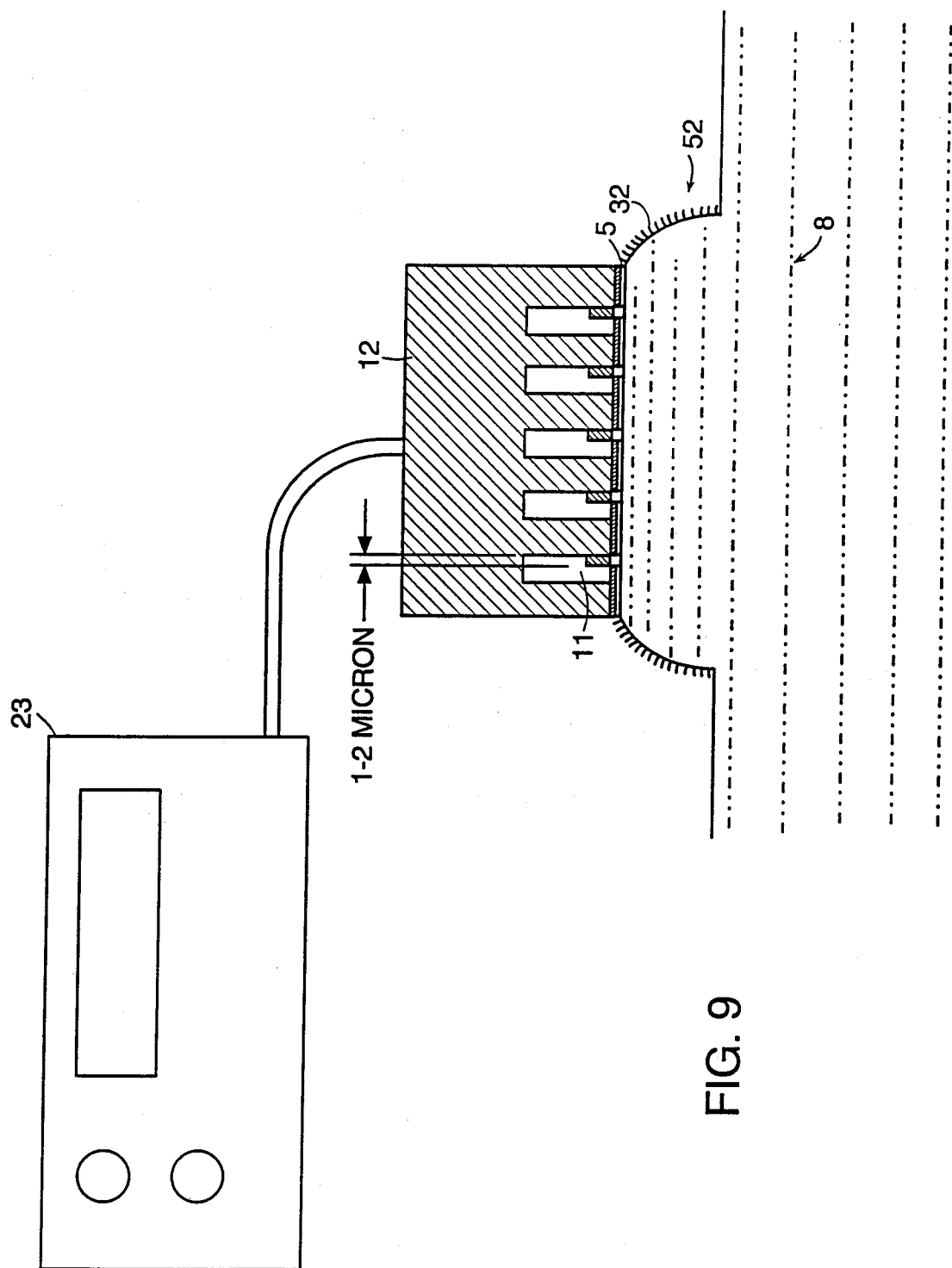


FIG. 8

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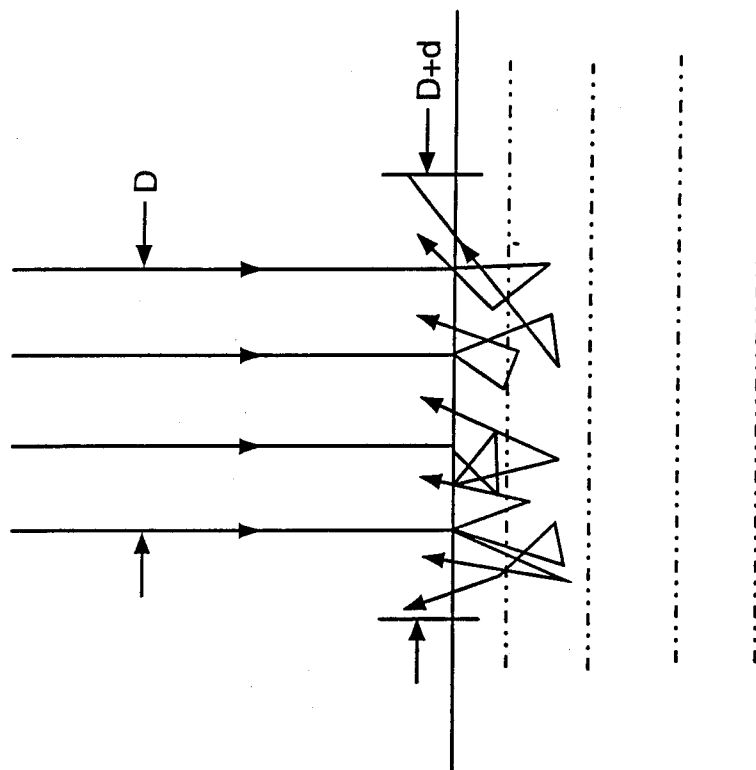


FIG. 10B

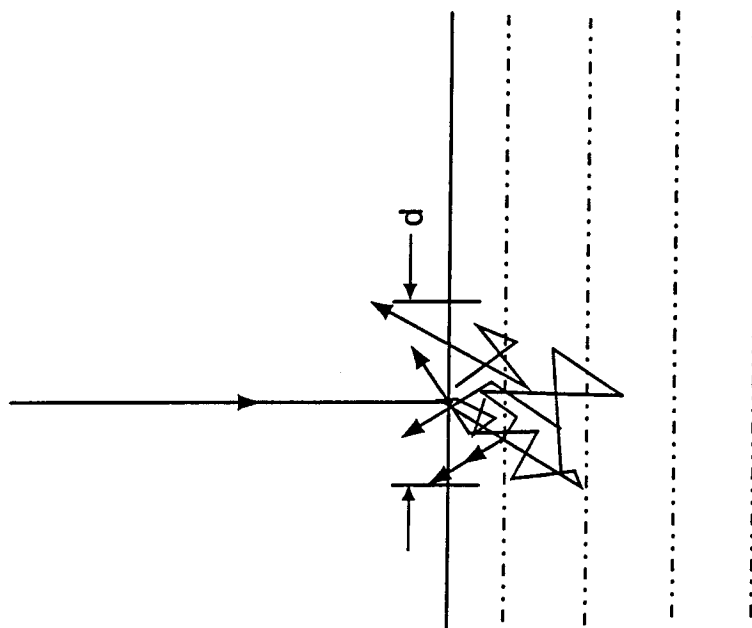


FIG. 10A

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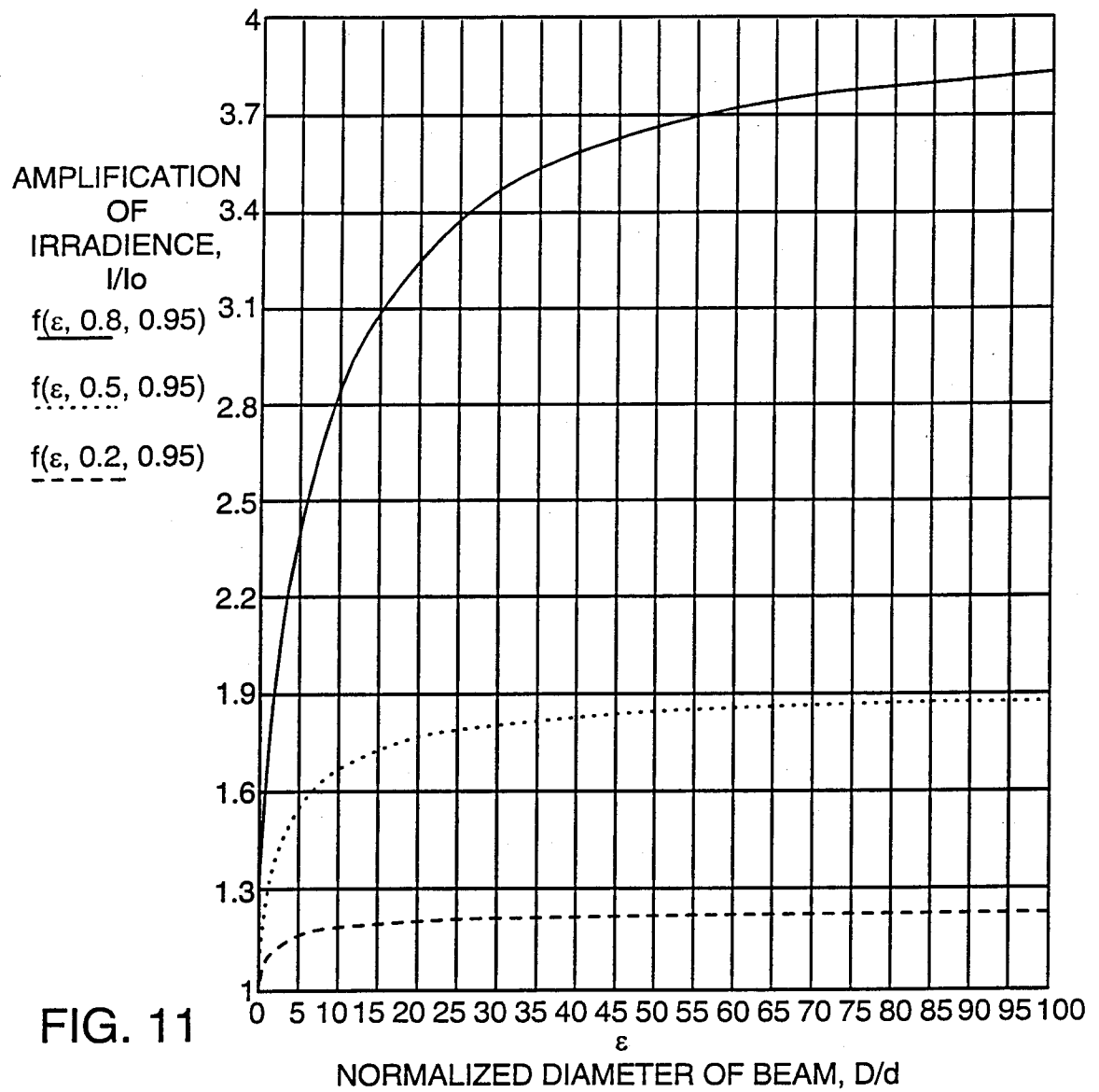


FIG. 11

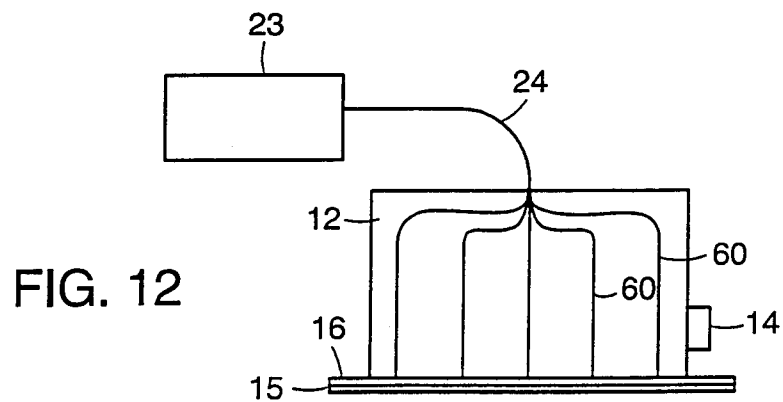


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/00869

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 820 625 A (YAMAZAKI IWAO ET AL) 13 October 1998 (1998-10-13) column 3, line 34 - line 53 column 4, line 61 -column 5, line 64 ---	1
X	WO 98 51235 A (GEN HOSPITAL CORP ;PALOMAR MEDICAL TECHNOLOGIES I (US)) 19 November 1998 (1998-11-19) page 18, line 18 - line 26 page 20, line 16 - line 24 ---	11-15,17
X	WO 99 46005 A (PALOMAR MEDICAL TECHNOLOGIES I) 16 September 1999 (1999-09-16) page 16, line 11 -page 17, line 20; figures 5A,5B --- -/--	11-15,25

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

27 June 2000

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 98 52481 A (COLLES MICHAEL JOHN ;MEDICAL LASER TECHNOLOGIES LIM (GB)) 26 November 1998 (1998-11-26) page 12, line 19 - line 36 -----</p>	11-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/00869

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5820625	A	13-10-1998	AU 696920	B	24-09-1998
			AU 1892897	A	02-04-1998
			CA 2203223	A	26-03-1998
			ES 2123461	A	01-01-1999
			IT MI970954	A	26-10-1998
WO 9851235	A	19-11-1998	AU 7568698	A	08-12-1998
			EP 0991372	A	12-04-2000
WO 9946005	A	16-09-1999	AU 3450799	A	27-09-1999
WO 9852481	A	26-11-1998	AU 7543298	A	11-12-1998

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60/235,814	27 September 2000 (27.09.2000)	US

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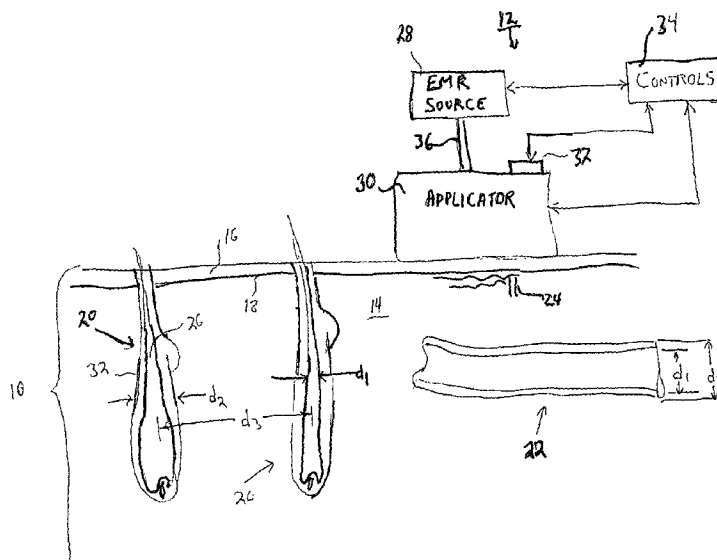
(74) Agent: **KRANSDORF, Ronald, J.**; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).

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[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR MEDICAL TREATMENT UTILIZING LONG DURATION ELECTROMAGNETIC RADIATION



(57) Abstract: A method and apparatus are provided for performing a medical procedure on a patient, for example a dermatological procedure, by use of electromagnetic radiation (EMR) having a relatively low peak power, and in particular a peak power low enough so as not to result in a phase change in the heater or chromophore absorbing radiation which would result in a significant reduction in its absorption, and of relatively long duration which is generally greater than, sometimes significantly greater than, the thermal relaxation time of the irradiated target.

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**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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**METHOD AND APPARATUS FOR MEDICAL TREATMENT
UTILIZING LONG DURATION ELECTROMAGNETIC RADIATION**

Field of the Invention

5 This invention relates to methods and apparatus for medical treatments using electromagnetic radiation, and more particularly to such methods and apparatus for treatment where the electromagnetic radiation is applied to a treatment area for a relatively long time interval at relatively low peak power.

Related Applications

10 This application relates to Serial No. 60/177,943, filed January 25, 2000 and Serial No. 60/235,814, filed September 27, 2000.

Background

15 For many years, electromagnetic radiation (EMR) from lasers, lamps and other sources, including microwave and radio frequency (RF) has been used to treat a variety of medical conditions in ophthalmology, dermatology, urology, otolaryngology and other areas. For example in dermatology, hair removal, treatment of various pigmented lesions, removal of unwanted vessels, skin resurfacing and the like are current applications. For all of these treatments, a chromophore, which may be naturally
20 existing in the patient's body or may be introduced into the body, absorbs at least some wavelength or wavelengths of the applied EMR and is heated as a result of this absorption. A natural chromophore can for example be water, melanin, hemoglobin, protein, or lipid. An artificial chromophore can for example be dye, ink, carbon particles or magnetic particles. The heating of the chromophore usually results in the destruction
25 of an unwanted hair follicle, pigmented lesion, tattoo, blood vessel, etc. to effect the desired treatment.

 However, all existing methods and apparatus for optical dermatology present problems. First, in most cases, in order to achieve the desired dermatological effect, substantial energy must be applied to the skin component being treated. Heretofore, in
30 order to get sufficient energy to the treated component, it has been necessary to use a relatively high peak power optical source, with for example one or more kilowatts of peak power generally being required in order to achieve long term hair removal. However, since the optical radiation must pass through the patient's epidermis to reach

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the treatment area, and since the epidermis contains melanin which is a chromophore at the wavelengths typically used for hair removal and certain other treatments, such high power applied to the skin can result in epidermal damage. While various techniques for cooling the epidermis during treatment have been discussed in the prior art, and these techniques do raise the energy threshold at which thermal damage occurs, it has been found that, while these techniques are effective for lighter skinned patients, for example patients having skin with lower Fitzpatrick skin type classification numbers, they frequently do not provide sufficient protection when treating darker skinned patients having, for example, Fitzpatrick skin types III-VI, and particularly for dark skinned individuals having skin types V and VI or tanned patients. This has meant that the benefits of optical dermatology treatments have heretofore not been available to a significant percentage of the population, and has limited the ability to treat exposed, and thus frequently tanned, parts of a patient's body, which are the parts on which treatment is most frequently desired.

Second, the requirement to generate high peak power has required the use of large, and relatively expensive, lasers and other optical sources. For example, to generate the requisite peak power using diode lasers, a laser head having as many as 100 diode bars may be required, depending to some extent on wavelength. In addition to the cost of the diode bars themselves, the use of such a large number of diode bars creates serious thermal management problems, further complicating the design and increasing the cost of the resulting diode laser device.

In addition, existing systems, which tend to apply energy to the skin component being treated over a relatively short time interval, can result in the explosion of the chromophore absorbing the heat, and thus in unwanted side effects, for example unsightly skin purpura, and in the generation of water vapor which may interfere with the efficient transfer of energy and/or heat to the component being treated. The process by which living tissues undergo thermal damage, including coagulative necrosis, is described in the scientific literature known to those skilled in the art, and will not be described here in any detail. High peak temperature of the chromophore can also cause chemical reactions which result in the formation of unwanted chemical substances. These substances can have a bad smell, this being a particular problem for hair removal, or can cause harm to the patient as a result of unpredictable effects of these substances on the body.

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The use of high peak power lasers or other EMR sources also results in dermatology treatments using such apparatus being dangerous in that improper operation of the equipment can cause potentially serious injury to a patient's skin, eyes, or other portions of the patient's body, and if not carefully operated, can also cause injury to the person operating the equipment. This has resulted in a requirement that most such equipment be operated either by a dermatologist or other physician or by a skilled professional under the supervision of a doctor. The high cost of the equipment coupled with the requirement for treatments to be performed by skilled professionals has resulted in optical or other EMR dermatology procedures being relatively expensive. This, coupled with the fact that most EMR dermatology procedures are not covered by health insurance, has significantly limited the availability of such treatments to the general public. Therefore, treatment procedures which both significantly reduce the cost of the equipment required and permit treatments to be performed by less highly trained personnel could significantly reduce the cost and enhance the availability of optical dermatology procedures to the general public.

It is also desirable to use feedback to control some EMR medical procedures, a patient parameter, for example skin temperature, being detected and utilized to control EMR energy, cooling and/or other treatment parameter, or if appropriate, to terminate treatment. However, feedback control is not practical with pulses of less than several ms, and works best with even longer pulse durations, in the order of 100 ms or greater. Feedback is another technique which permits less trained personnel to safely operate the equipment.

Further, for the EMR dermatology treatments discussed above, the chromophore absorbing radiation and being heated thereby and the target to be acted on for destruction or other treatment generally occupying the same area, the chromophore being the treatment target. However, there are applications in EMR dermatology where the treatment target is not a chromophore and a chromophore does not exist in the immediate area of the treatment target; or in another words where non-uniform absorption exists in the target area, part of the target area exhibiting weak absorption or no absorption at all, while other parts show significant absorption. In these cases, damage to weakly absorbing/nonabsorbing portions can only be achieved by heat diffusion from highly pigmented, strongly absorbing portions of a target area, such portions frequently being referred to hereinafter as "heater portions" or simply as "heaters". However, standard

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theories heretofore used for developing EMR radiation treatments, including the theory of selective photothermolysis, are only applicable where the chromophore and destruction target occupy substantially the same space and do not provide a reliable basis for developing treatment protocols for target areas having non-uniform absorption characteristics, and in particular where the destruction target has little or no absorption at the applied wavelength(s) and is spaced from any heater portion.

Finally, there are EMR treatments where enough energy cannot be applied to the target during a single treatment to effect the desired therapeutic result without undesired side effects, for example epidermal damage. However, with standard EMR treatments, the chromophore is generally destroyed during the treatment, so that weeks or even months must pass before the chromophore regenerates sufficiently for another treatment to be performed. It would be far preferable if two or more EMR treatments could be performed during a single treatment session, or at least within days of each other, rather than within weeks or months.

Many of the problems indicated above for dermatology can also arise when performing other EMR medical procedures, including the need to protect the patient's epidermis and treatment of targets having non-uniform absorption.

A need therefore exists for an improved method and apparatus for performing optical dermatology and other EMR medical procedures which overcomes the various problems indicated above, and in particular which facilitates treatment of non-uniformly absorbing areas and of dark skinned/tanned patients, which is both less expensive and safer than existing procedures, which permits multiple treatments during a single session, or closely spaced sessions, and which facilitates feedback control of treatments.

Summary of the Invention

In accordance with the above, this invention provides a method and apparatus for performing a medical procedure on a treatment area of a patient's body, which procedure may, for example, be a dermatology procedure such as hair removal, treatment of vascular lesions or collagen restructuring for wrinkle removal or other purposes. The method and apparatus involve applying electromagnetic radiation (EMR) of an appropriate wavelength from a source of such EMR through a suitable head to the treatment area. For preferred embodiments, the EMR is optical radiation, for example, coherent optical radiation from a laser or non-coherent optical radiation from a flash

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lamp, filament lamp, LED or other suitable source. Key features of the invention are the power profile for the applied radiation and the duration for application of radiation to the target area.

In accordance with one aspect of the invention, the power profile for the applied radiation has an average power (P_a) sufficient to effect the desired result over the application duration and a peak power (P_p) which does not result in destruction of the chromophore or heater. The duration of radiation application to the target area is longer than the thermal relaxation time (TRT) of the target area, being long enough for sufficient energy for the procedure to be applied at the power profile to the treatment area. For this embodiment, the duration of radiation application can be up to 20 seconds and more, particularly for hyperthermia treatments, and P_p is preferably less than 500 watts. For some continuous wave embodiments of the invention, P_p and P_a for the radiation over the duration of application are roughly the same.

For this invention:

- The EMR wavelength should be chosen to maximize contrast between the absorption coefficient of the pigmented area or heater and that of the tissue surrounding the target area. This postulate is identical to the case of classical selective photothermolysis.
- The EMR power should be limited to prevent the pigmented heater area from destruction or from otherwise losing the ability to absorb, but must be sufficient to achieve a heater temperature higher than the target damage temperature.
- The pulsewidth should be made shorter than or equal to the thermal damage time (TDT), which can be significantly longer than the thermal relaxation time (TRT) of the target. TDT is the time required for irreversible target damage with sparing of the surrounding tissue.

For some embodiments, irradiation is applied to heat at least one chromophore in the treatment area and the peak power is selected so as to heat the at least one chromophore only to a selected temperature, which temperature is below that at which the chromophore undergoes a change which results in significant loss of absorption at the applied wavelength or wavelengths. For example, the temperature to which the chromophore is heated may be no more than approximately 100-110° C so as to avoid vaporization of water in the tissue. For some embodiments, the procedure is hair

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removal, the chromophore is melanin within a hair shaft of the hair follicle and the duration of radiation application is sufficient for heat transfer from the hair shaft to the outer root sheath of the follicle to damage stem cells located thereat. The chromophore may also be another chromophore either located within the hair follicle or introduced
5 therein which results in the power profile and duration being sufficient to cause destruction of stem cells at an outer root sheath of the follicle, a papilla for the follicle and/or other critical follicle cells.

For another embodiment, the procedure is wrinkle removal, the chromophore is melanin at the dermis/epidermis (DE) junction, and the power profile and duration are
10 sufficient to heat collagen in the papillary dermis sufficiently to restructure such collagen. For still other embodiments, the procedure is destruction of vascular lesions, the chromophore being at least hemoglobin or water of the blood in the vascular lesion and the duration being sufficiently longer at the power profile for heating and denaturation of the wall of the vessel. Water may also be the chromophore for various
15 other treatments, including treatments for skin rejuvenation or wrinkle removal.

In accordance with still another aspect of the invention, the wavelength of the EMR from the source is absorbed by melanin in the patient's epidermis, including at the dermis/epidermis (DE) junction, and the power profile and duration are such that heat generated as a result of EMR absorption in epidermal melanin can migrate to the skin
20 surface and be removed concurrent with irradiation, thereby controlling temperature increase in the epidermis during irradiation. In accordance with still another aspect of the invention, the treatment area has a target area with a thermal relaxation time and the duration is longer than this thermal relaxation time. In particular, the target area includes a heater part or portion which is highly absorbing at the wavelength(s) of the EMR
25 source and the EMR radiation is applied at least to such heater portion of the target area for a duration significantly greater than the thermal relaxation time of the target area. The target area also has a thermal damage time (TDT) which is the time required at the applied power profile for the entire target area to reach a thermal destruction temperature, and the duration of the optical radiation is substantially equal to such TDT.

30 More specifically, the duration of the optical radiation (T) is equal ($TDT - \delta$) where δ is roughly the propagation time for the front of the heat from the heater portion to a non-heater portion of the target furthest from the heater. TDT and TRT may be

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related such that $TDT = TRT \cdot r(x, \Delta)$, where x is a geometrical factor and Δ is a temperature factor. More specifically, $x = d_2/d_1$, where d_1 = size of heater portion and d_2 = size of total target; and $\Delta = (T_2 - T_0)/(T_1 - T_0)$ where T_0 is target and heater temperature before irradiation, T_1 is the heater temperature and T_2 is the temperature at which irreversible thermal damage of the target area generally occurs. Where the target is a hair follicle, and the heater includes a pigmented hair shaft or hair matrix in the follicle, TDT is the time required for heat to the thermal destruction temperature to reach an outer sheath of the follicle. Similarly, where the target is a blood vessel, and the heater includes blood in the blood vessel, TDT is the time required for heat to the thermal destruction temperature to reach through walls of the blood vessel in the target area. Where the target is collagen in the papillary dermis, and the heater is melanin at the DE junction, TDT is the time required for heat at the thermal destruction temperature for collagen to reach a desired depth in the papillary dermis. For substantially all applications, the power profile should be such that, at TDT, the entire target area is at a temperature of at least the thermal destruction temperature, but substantially no tissue outside the target area is at or above the thermal destruction temperature.

To maximize energy or power delivered to a target inside a patient's body, it is generally desirable to cool the patient's skin in an area over the target area to remove heat from at least the patient's epidermis. Such cooling may be active cooling, for example having a chilled plate, lens, waveguide or the like in contact with the patient's skin, applying a cryogen spray to the patient's skin, gas/liquid flow across skin surface or other known contact or non-contact active cooling techniques, or may be passive, relying on heat diffusion from the skin surface.

In accordance with another aspect of the invention, the power profile of applied radiation results in heating of the heater to a temperature T which is greater than the thermal destruction temperature for at least a portion of the target to be damaged, but less than a collapse temperature at which the heater portion undergoes a change which results in significant loss of absorption at the at least one wavelength. The heater part of the target area may be a naturally-occurring chromophore in the patient's body, or may be an artificial chromophore introduced to the target area. Where the medical procedure is hair removal, the heater may include a hair shaft or hair matrix in the hair follicle which has a collapse temperature of up to 250° C, the radiation duration in this case being up to approximately 20 seconds. Where the medical procedure is removal of vascular lesions

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or collagen remodeling, the duration of radiation application may, for example, also be up to approximately 20 seconds.

In accordance with still another aspect of the invention, the target area includes at least one highly absorbent heater portion and at least one non-heater portion having weak absorption to no absorption, the at least one non-heater portion being spaced to varying degrees from the at least one heater portion. Electromagnetic radiation from a suitable source is applied to at least the heater portion(s) of the target area, the radiation including at least one wavelength highly absorbed by the heater portion(s) and having a power profile which heats the heater portion(s) to a temperature T greater than the thermal damage temperature for the portion(s) of the target area to be damaged, but less than the collapse temperature at which heater portion(s) undergo a change which results in significant loss of absorption at the applied at least one wavelength, the radiation being applied for a duration sufficient with the power profile to permit heating of substantially all of the target area from the heater portions to a temperature sufficient to accomplish the medical procedure. Where there are a plurality of target areas in an aperture being irradiated by the optical radiation, each of which areas is of a size d_2 , and the centers of the target areas are spaced by a distance d_3 , the ratio of fluence F_{NS} at which damage outside the target areas occur to fluence F_s at which selective damage of a complete target area occurs is $F_{NS}/F_s = (d_3/d_2)^n$, where n is dependent on target shape. The ratio F_{NS}/F_s has been found to drop significantly for $Y=d_3/d_2 < 5$.

In accordance with still another aspect of the invention, the wavelength utilized, in addition to being appropriate for the medical procedure being performed, is also absorbed by melanin in the patient's epidermis, including at the DE junction. In this case, the EMR has a power profile and duration which are sufficient to effect the medical procedure and are such that heat generated as a result of EMR absorption in the epidermal melanin can migrate to the skin surface and be removed concurrent with irradiation, thereby controlling temperature increase in the epidermis during irradiation. Active cooling may be applied to the skin surface to facilitate the removal of heat therefrom.

In accordance with still another aspect of the invention, the power profile is such that the temperature of the heater is maintained substantially constant for the duration of EMR application. This power profile may for example result in an optical power which decreases substantially exponentially for the EMR duration.

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The foregoing and other objects, features and advantages of the invention will be apparent in the following more particular description of preferred embodiments of the invention as illustrated in the accompanying drawings.

5

Brief Description of the Drawings

Fig. 1 is a schematic representation of a portion of a patient's skin and of a system suitable for practicing the teachings of this invention positioned adjacent thereto;

Fig. 2 is a diagrammatic representation of a biological target with a spaced chromophore/heater and target area;

10 Figs. 3a and 3b are diagrams illustrating optical power versus time and temperature versus time respectively for a rectangular EMR pulse mode, while Figs. 3c and 3d are diagrams illustrating power versus time and temperature versus time for a rectangular temperature pulse mode respectively;

15 Figs. 4a-4c diagrammatically illustrate three geometrical shapes, namely, plane, cylindrical and spherical, respectively, utilized in various examples;

Figs. 5a and 5b are diagrams illustrating temperature versus location for the rectangular EMR pulse mode and rectangular temperature pulse mode, respectively, at different times, Fig. 5c being a cross-section through an illustrative hair follicle;

20 Figs. 6a-6c are diagrams showing the ratio of $r(x, \Delta) = \text{TDT/TRT}$ as a function of a geometrical factor x for two heating modes for a plane target, cylindrical target and spherical target, respectively;

Fig. 7 is a diagram of temperature versus position relative to a hair shaft for a cylindrical target for different temperatures of the hair shaft;

25 Fig. 8 is a chart showing calculated temperature distribution as a function of depth for a cooled surface (10°C) and a laser pulse duration of 1 second at roughly 150 J/cm^2 ;

Figs. 9a-9d are charts illustrating temperature versus depth for pulse durations of 3 ms, 10 ms, 100 ms and 300 ms, respectively;

30 Figs. 10a-10c are diagrams illustrating the dependence of pulse width to hair shaft diameter for various densities of hairs;

Fig. 11 is a diagram illustrating the relationship of pulse power and duration for various hair and skin types;

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Fig. 12 is a diagrammatic representation of an ideal model for cylindrical targets with equal spacing; and

Figs. 13a and 13b are diagrams illustrating the dependence of thermal destruction time, fluence F_S required to produce selective damage and F_{NS} , the fluence required to
5 produce unselective tissue damage on the density factor for the targets.

Detailed Description

Fig. 1 is a schematic representation of a patient's skin 10 and of an exemplary system 12 for applying electromagnetic radiation (EMR) to the patient's skin for treating
10 a variety of medical conditions. The skin 10 consists of a dermis 14 covered by an epidermis 16, there being a dermal epidermal (DE) junction 18 at the intersection of these two skin layers. Epidermis 16 is generally relatively thin, extending perhaps 30 to 200 microns from the skin surface, while the dermis 14 is thicker, extending on average approximately two to five mm from the DE junction. Pigmentation, which determines
15 the color, and in particular the darkness, of a person's skin is contained primarily in epidermis 16 in the form of melanin which exists primarily on the epidermis side of the DE junction, but, particularly for darker skinned individuals (including tanned individuals), also exists throughout the epidermis. The darkness of a person's skin is frequently quantified on a Fitzpatrick scale, which ranges from I for very light skinned
20 individuals to VI for very dark-skinned individuals.

There are many components within the skin on which EMR dermatological procedures may be performed. These include hair follicles 20, blood vessels 22, collagen 24 in the papillary dermis, etc. Hair follicles 20 may for example be irradiated to remove unwanted hair, for example facial or leg hair on women, and may in some cases also be
25 irradiated to stimulate hair growth. The mechanism for stimulation can be soft reversible damage of the follicle matrix to stimulate blood delivery to the papilla. Treatment may also be performed to remove blood vessels 22 or other vascular lesions, which may include leg veins, spider veins, varicose veins or other blood vessels which either cause discomfort to the patient or which are consider unsightly and the removal of which is
30 desired. Collagen 24 may be non-invasively remodeled, existing collagen being destroyed to facilitate regrowth of new collagen, for wrinkle removal and other purposes. The teachings of this invention may also be used for other dermatological treatments and

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for certain subdermal treatments, such as fat removal, acne (sebaceous gland) treatment or for other medical procedures normally performed by selectively applying EMR of an appropriate wavelength to a selected treatment area.

Apparatus or system 12 illustrates in schematic form the basic components of a system or apparatus for applying EMR radiation to a treatment area of a patient. Apparatus 12 includes a source of EMR 28, an applicator 30 through which the EMR is applied to the skin of the patient, a mechanism 32 which as shown operates in conjunction with applicator 30 to remove heat from the surface of the patient's skin, or in other words to cool at least the epidermis of the patient, and controls 34 which operate in accordance with the teachings of this invention to control, for example the power profile and/or duration of EMR from source 28 and/or to control applicator 30 to achieve a desired power profile, wavelength profile and/or duration for EMR applied thereto from source 28 and to control component 32 as required to achieve a desired cooling of the patient's skin.

EMR source 28 may be any of a variety of EMR sources currently or hereafter used or developed for EMR medical procedures, including various types of lasers, for example solid-state lasers and diode lasers, fiber lasers, flash lamps, filament lamps and other sources of incoherent optical radiation, a microwave source, an RF source, etc. When EMR source 28 produces radiation at one or more wavelengths, or wideband radiation, either of which includes wavelengths which are not desired for a particular treatment, source 28 and/or applicator 30 may include filters, wavelength shifters or other appropriate components to eliminate undesired wavelengths and/or to enhance desired wavelengths.

Further EMR source 28 may be a pulse source which remains on for a selected duration, may be a source which generates a sequence of pulses in rapid sequence, with short spaces between adjacent such pulses, such sequence of pulses being generated for a duration which is equal to the desired duration for the EMR signal, or may be a continuous wave (CW) signal, such CW signal being either continuously on or a sequence of short pulses of the type indicated above with small spaces between adjacent pulses. The power supply can also control the power profile of the EMR to obtain an optimum pulse shape which maximizes heating of the target and minimizes overheating of the epidermis. A CW source and/or the applicator 30 used therewith may be moved at a selected rate over a treatment area so as to provide a selected dwell time or pulse

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duration over each target area. Thus, when the terms “pulse duration” or “signal duration” are used herein, such terms should be interpreted to mean the total dwell time of any of the above EMR signals on a selected target area or portion thereof.

EMR from source 28 is applied through a suitable conduit 36 to applicator 30.

5 For example, where source 28 is a source of optical radiation, conduit 36 may be an optical fiber or bundle of optical fibers. Alternatively, applicator 30 may be a radiation delivery head having EMR source 28 physically mounted therein. Other arrangements known in the art for delivering EMR radiation from a source to an applicator may also be utilized.

10 While applicator 30 is shown in Fig. 1 as being in contact with the patient's skin, and for most applications an applicator in contact with the patient's skin is preferred, this is not a limitation on the invention, and in some applications a non-contact applicator may be used, either with passive cooling, cryogenic spray cooling, etc., the specific applicator utilized varying with application. For example, where the applicator is also
15 being utilized to cool or remove heat from the skin surface, good thermal contact is clearly preferred. Contact may also permit more efficient transfer of radiation into the patient's skin and may facilitate retro-reflection of radiation which, as a result of scattering in the skin, leaves the skin and is reflected back by the head toward the treatment area. Depending on the nature of the radiation applied, applicator 30 may be
20 stationary over a treatment area for the duration of a given EMR pulse or signal or, where source 28 is a source of CW radiation, applicator 30 may move over the skin at a rate so that the dwell time of the radiation from the applicator over each portion of the treatment area is equal to the desired duration of the EMR signal. Applicator 30 may also determine or control the aperture size for the applied radiation.

25 Mechanism 32 may be any of a variety of components known in the art for cooling or removing heat from a patient's skin. For example, applicator 32 may be a waveguide, lens or plate of sapphire or other suitable material through which the radiation is applied to the patient's skin, the material of the waveguide/lens/plate having good heat transfer properties and being cooled by a thermoelectric device 32 being in
30 contact therewith or by passing a cooling fluid, for example a cryogenic fluid, water, gas, etc., over the waveguide/lens/plate either periodically or continuously in manners known in the art. Applicator 30 could also be a block of a metal or other material having good heat transfer properties with open channels through which radiation is applied to the

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patient's skin, the block being cooled using one of the techniques previously indicated. For some embodiments, component 32 may be utilized to first heat the person's skin to the depth at which treatment is to occur and then used to cool the epidermis prior to irradiation. (See for example co-pending application Serial No. 09/078,055, filed May 13, 1998, the content of which is incorporated herein by reference, for a more detailed discussion on metal block applicators and the preheat/precooling feature). However, the teachings of this invention may eliminate the need for such precooling.

Controls 34 may be manually operated, but preferably include a microprocessor or other suitable processor programmed to control the operation of EMR source 28, applicator 30, and cooling component 32 in the manner to be hereinafter discussed to achieve a power profile and duration for the applied radiation which conform to the teachings of this invention. Controls 34 may receive selected inputs from source 28, applicator 30, temperature mechanism 32 and/or other components indicating such things as temperature of various system components and/or of the patient's skin.

As indicated earlier, there are at least two situations where conventional EMR dermatology treatments are not effective. These situations are (i) where the patient has dark skin, for example, patients with Fitzpatrick's skin types V and VI; and (ii) where the treatment area has non-uniform absorption characteristics such that a heater portion of the target area having high absorption at the applied EMR absorbs energy from the EMR and is heated thereby, the heater portion being spaced from portions of the target which absorb little or no EMR at the applied wavelength, but which are to be thermally destroyed or otherwise thermally treated. In the former situation, in accordance with the teachings of this invention, it has been discovered that when the EMR is applied at relatively low power over an extended time interval, heat produced as a result of EMR absorption by melanin in the epidermis has time to move to the skin surface and be removed, particularly if the skin surface is actively cooled, this parallel cooling of the epidermis during EMR irradiation of the target area permitting treatment to be effected without causing damage to the patient's epidermis, even for patients having Fitzpatrick's V and VI skin. In the second case, in addition to the parallel cooling effect indicated above, the relatively long duration EMR signal also permits time for heat to diffuse from heater portions of the target area to the non-pigmented portions of the target to achieve the desired thermal destruction or other treatment of such non-pigmented portions. However, since the heater must remain intact to permit heat diffusion therefrom for the

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period required for heat to the desired temperature to diffuse to the non-absorbing target portions, the energy applied to the heater must, at least for the required pulse duration, be below the threshold at which the heater undergoes a phase change or transition which results in a significant loss of absorption at the EMR wavelengths, for example as a
5 result of bleaching, melting, boiling, bubble formation or other destructive process on the heater. Thus, as discussed in far greater detail later, the invention involves the use of EMR signals of relatively low peak power delivered over a relatively long duration in order to achieve the objectives indicated above. Such low peak power, long duration EMR signals also permit use of lower cost EMR sources and, by permitting much lower
10 power EMR sources to be utilized, are far safer to use, permitting in some instances further cost reductions by having treatments performed by less highly skilled and trained, and thus less expensive, individuals. Since the chromophore remains intact, even when a treatment is completed, multiple treatments may be performed during a single treatment session or within days of each other to permit safer, more effective treatment. The
15 extended time interval of the treatment also facilitates feedback control.

While in the discussion to follow, the long duration EMR signals are sometimes referred to as "pulses," it should be understood, as indicated earlier, that long duration EMR signals in accordance with the teachings of this invention may be obtained in at least three different ways. First, the EMR signal may be applied as a single pulse of the
20 desire duration. Such a pulse may for example be achieved by operating EMR source 28 for the prescribed duration, by using a shutter to pass radiation from the source to the target for such duration or by other techniques known in the art. When the EMR source pulses on and off at a relatively high rate, such source may be used as long as the maximum spacing between adjacent pulses is very short relative to the EMR duration
25 and the average power of the pulse train for the duration of the EMR signal is sufficient to effect the desired treatment. The latter condition is necessary in order for requisite power and energy to be achieved without requiring a high peak power source. The third way in which the EMR signal duration may be achieved is to use a continuous wave (CW) source, which source may be a high repetition rate, high duty cycle source of the
30 type indicated for the second option, and passing this source over the treatment area in for example the manner indicated in co-pending Application Serial No. 09/078,055 filed May 13, 1998, the signal duration in this case being the dwell time of the CW signal source over the target area. For this embodiment, the head delivering the EMR energy

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would be moved at a much slower rate than for embodiments where the teachings of this invention are not practiced.

Considering first the objective of achieving more effective parallel cooling so as to be able to more safely treat all patients, and in particular to be able to safely treat dark
5 skinned (including tanned) patients, the problem with dark-skinned patients stems from the fact that for all patients there is some melanin concentration in the epidermis at the dermal/epidermal (DE) junction. The melanin concentration in this area increases for darker skinned individuals, and, as skin color darkens, melanin tends to increasingly appear throughout the epidermis. For very dark skinned patients, for example patients
10 with skin types V and VI, there is significant melanin concentration at the DE junction, with lesser amounts of melanin throughout the epidermis. Thus, for treatments at a radiation wavelength which is preferentially absorbed by melanin, for example hair removal treatments where melanin in the hair shaft, hair matrix and other portions of the follicle is being targeted, significant heating of epidermal melanin can also occur,
15 making it difficult to perform such treatments on dark skinned individuals. Thus, while heat from melanin absorption in the epidermis can migrate to the skin surface to be removed, either by air, by evaporating cryogen on the skin surface, by a cooled element in contact with the skin surface, or by other suitable means in as little as 0.1 milliseconds for melanin near the surface of the epidermis (melanin being near the surface at the
20 epidermis for dark skinned individuals and/or for skin areas having an exceptionally thin epidermis), it typically takes at least 10 ms for heat from melanin at the DE junction to reach the skin surface, and generally takes significantly longer. It has been found that for optimal parallel cooling, parallel cooling being defined for purposes of this invention as skin cooling which occurs as a result of heat escaping from the skin's surface during
25 irradiation, a radiation duration of at least 50 ms, and preferably 100 ms or more, is required.

In particular, while the time required for the front of the heat to flow from the DE junction to the skin surface may on average be approximately 10 ms, the epidermis also has a finite capacity for transferring heat per unit time. Thus, while some heat will be
30 dissipated from the DE junction through the mechanism of parallel cooling with an irradiation duration of 10 ms, the epidermis does not have the capacity to remove most of the heat accumulated in the melanin at the DE junction during this time interval. It has been found that in order to hold down the temperature at the DE junction, low peak

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power irradiation for a duration of at least 100 ms is normally required, this duration being sufficient for the heat removal capacity of the epidermis to permit sufficient heat transfer to the skin surface so as to assure against overheating of the epidermis in general, and the DE junction in particular. Longer durations for the applied irradiation and/or more aggressive active cooling of the skin surface can further reduce or even eliminate heat rise in the epidermis, thereby enhancing both safety and patient comfort for EMR medical treatments in general and for optical dermatology treatments in particular.

With such long pulse durations, and with the lower peak power sources which may be utilized to deliver a desired energy to the target or treatment area with such long treatment times, it has been found that all types of skin, including skin types V and VI, may be treated safely without incurring thermal damage to the epidermis.

Further, the lower peak power required, particularly for pulse durations in excess of 100 ms, and in some cases in ranges up to several seconds, for example up to 20 seconds and more, permits optical sources having a peak power in the 100's of watts range, for example 100 to 200 watts, to be utilized, and possibly even less, permitting for example an 800 nm laser diode head having only one to three laser diode bars, as opposed to 10-100 bars for shorter pulse, to be utilized. Similar improvements can be obtained at other wavelengths. In some applications, this may even permit the EMR source to be a standard incandescent light bulb or other standard light source (for example, even the sun), appropriate filtering or wavelength shifting sometimes being required or desirable when such wide-spectrum sources are utilized. As is discussed in greater detail later, in some applications where low power sources are utilized, exposure times in the range of minutes, or in some cases hours, may be appropriate. The low peak power, long pulse duration treatment protocols discussed in this paragraph permit optical dermatology procedures to be performed with smaller, lighter and significantly less expensive equipment, and also significantly simplifies thermal management problems, further reducing equipment size and cost.

Another significant advantage of utilizing the low peak power, long pulse technique of this invention is that its safer for the patient. In particular, while prior art systems can, if not properly utilized, cause damage to the patient's skin or, when used to treat for example wrinkles or hair on a patient's face, have the potential for causing eye damage or damage to other organs of the patient's body, the potential for harm to the

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patient as a result of improper use of the treatment apparatus is significantly reduced when low peak power optical sources are utilized. Potential injury to the operator is also significantly reduced. Further, the low peak power, long duration pulses allow sufficient time for the condition of the patient's skin or other treatment parameters to be monitored
5 and utilized to control treatment parameters, for example EMR power and/or cooling, and to terminate treatment in the event a dangerous condition is detected before skin damage occurs. Such feedback control and protection are not practical with the short pulses currently utilized. Thus, while current techniques require that the treatment be performed either by a dermatologists or other physician, or at least by a highly skilled
10 technician under the supervision of a physician, the low peak power apparatus which may be utilized in accordance with the teachings of this invention may permit hair removal, skin resurfacing and other dermatological procedures to be performed by less highly trained people, and possibly by cosmologists, barbers and the like. Home use may even be possible, particularly if power is reduced so as to provide only "hair
15 management," for example functioning as a long term razor, rather than permanent removal. This, coupled with the potential for significantly lower cost equipment, will dramatically reduce the costs of such optical dermatology treatments, making them available to a far larger population.

In addition to the advantages discussed above which arise from the use of low
20 power, long duration EMR signals for performing EMR dermatology, such signals are also useful where the target area has non-uniform absorption of radiation for the wavelengths of the applied EMR signal. Such non-uniform absorption, which is common for the human skin, means that within a given target area there are portions which are highly absorbent at the wavelength or wavelengths of the EMR source and
25 there are portions in the target area which are either weakly absorbent of such radiation or totally non-absorbent. Where a dermatological treatment requires thermal destruction of such non-absorbing or weakly absorbing portions, such result has not been possible with prior art high peak power, short duration EMR signals, frequently resulting in less than ideal results for various dermatological treatments including, but by no means
30 limited to, hair removal, elimination of vascular lesions and skin resurfacing through collagen remodeling.

However, the low power, long duration signals of this invention are capable of effecting such treatments. More specifically, the procedure using a pulse duration

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$\tau < \text{TRT}$ becomes inapplicable when the target and the chromophore or heater are spatially separated or the absorption of the target is non uniform over its volume, and the treated part of the target has weak or no absorption, but another part of the target has significant absorption. If this is the case, the weakly absorbing part of the target has to
5 be treated by the diffusion, radiation, convection or other transfer mechanism of heat from the strongly absorbing heater part. For example, for permanent hair removal, in accordance with current knowledge, it is necessary to damage all follicle structure up to the connective tissue sheath or the stem cells located in the bulge area at the outermost layer of the outer root sheath. Damage or destruction of follicle matrix and/or papilla are
10 also desirable for hair removal. The heaters with high absorption of light are the melanin-containing hair shaft and matrix cells. But the targets to be damaged include stem cells and other follicular structures such as the papilla that do not have the required chromophores. These targets can be damaged by heat diffusion from the hair shaft or the matrix cells to the surrounding follicular structures that do not contain a useful
15 chromophore. In order to accomplish this, the hair shaft or other chromophore must continue to absorb for the entire pulse duration and must not become thermally isolated from the remainder of the follicle which is to be damaged or destroyed.

Another example of spatially separated target and heater/chromophore is the treatment of telangiectasia, or leg veins. Permanent closure of the vessels probably
20 requires coagulation of the vascular wall. In this case the heater is blood, due to the high absorption of hemoglobin and/or water. Coagulation of the wall requires heat diffusion from the blood into the wall.

When properly controlled, this treatment procedure can be used to safely deliver a clinically-effective thermal dose to a prescribed region surrounding the light-absorbing
25 chromophores or heaters to cause a thermal lesion or a volume of denatured or coagulated tissue as required, while avoiding an absorption degrading change to the chromophore. This assumes that the chromophore used (e.g., water, melanin, hemoglobin) has a higher threshold for thermal damage than the surrounding tissue, and that the energy delivered is such that it does not cause the chromophore to explode or be
30 otherwise be altered so as to lose or degrade its ability to absorb radiation.

The thermal dose is calculated according to formulas known to those skilled in the art, and is an Arrhenius integral of the applied temperature over the time of treatment. The boundaries demarcating treated tissue from untreated healthy tissue outside the

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treatment volume are sharp due to the Arrhenius nature of the thermal dose delivery, such that tissue outside the treatment volume receives less total thermal dose than that lying within the treatment volume. It should be noted that the treatment volume may extend beyond the region being irradiated, and depends on the properties of the
5 irradiating source as well as the tissue properties. Additionally, cooling by external means (e.g. parallel cooling) or internal means (by thermal diffusion or blood perfusion) affect the final outcome of the treatment, and in particular heating outside the treatment volume or target area, for example epidermal and possible dermal tissue above the target area.

10 Thermal damage of such types of targets requires heat deposition of sufficient power in the heaters, and good heat transfer from the heaters to the targets. Heat deposition depends on the coefficient of absorption of the targets and the power density of the EMR within the tissue. Heat transfer depends on the distance between the target and the heater and the heat transmission coefficient of the tissue. However, at a
15 sufficiently high temperature, both the absorption coefficient of the heater and the heat transmission coefficient from the heater to the other targeted tissues may be compromised by phase transition and destructive processes like bleaching, melting, boiling, and bubble formation for the heater, and possible for tissue adjacent the heater. To prevent these undesirable effects, the peak temperature of the heater has to be limited
20 by a prescribed maximum value, T_{Imax} , called hereafter the "heater collapse temperature." Simultaneously, to ensure the permanent damage of the whole target, the temperature should exceed some minimum prescribed value, "the thermal damage temperature," T_2 , over the target volume. The latter temperature is smaller than the collapse temperature. The temperature within the tissue between the target and the
25 heater should be below the boiling temperature of water to prevent thermal isolation of the target from the heater and other adverse effects. To meet the temperature limitations above, the power of the EMR should be controlled, and the pulse width has to be sufficiently long to deliver the energy needed. The thermal damage time (TDT) of the target is the time for the target temperature to exceed T_2 for a duration sufficient for
30 irreversible target damage without damaging the surrounding tissue. TDT is thus the time to generate a temperature T_2 at the target by heat diffusion from the heater to the target. Because the temperature gradient is not sharp, part of the heat will leak from the target, resulting in the heated area being larger than the target. Nevertheless, TDT may

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be many times as long as TRT of the whole target while still achieving selective damage of the target with sparing of the surrounding tissue. The optimum pulsewidth τ_0 of the EMR pulse should however be slightly shorter than or equal to TDT.

The mechanism for selective damage of the target by heat diffusion is illustrated in Fig. 2, this mechanism relating to therapeutic and medical treatments using electromagnetic radiation to selectively damage targets that are spatially separated from the light absorbing chromophore. In Fig.2, the distance between the heater and the target is d . Photons from an EMR source are absorbed by the heater. The EMR power density and pulse length are established so that the temperature of the heater T_1 should be below the thermal damage threshold $T_{1\max}$ of the chromophore. Heat is transferred from the heater to the target by thermal diffusion or another mechanism such as by shock waves or steam.

Confined thermal damage of the target is achieved when the temperature of the target reaches T_2 , but the external surrounding tissue remains below that temperature. This thermal damage temperature T_2 depends on the duration and the shape of the heating pulse. For proteins, T_2 is between 42-80°C, depending on the dwell time (i.e., determined by Arrhenius integral). It is usually not possible to damage the target without damaging the tissue between the target and the heater. After the end of the EMR pulse, the temperature of the target will continue to rise to a maximum some time later. The time delay between the end of the EMR pulse τ and moment of peak temperature of the target, that is TDT, is denoted by δ (i.e., $\tau = \text{TDT} - \delta$). The pulse width should thus be equal to or shorter than the TDT, δ being significantly shorter than the TDT in most cases. Therefore, the pulsewidth for selective treatment may be considered to be equal TDT (i.e., $\tau = \text{TDT}$).

As a first example, a target that is a highly pigmented long cylinder with diameter d_1 surrounded by a treatment area with diameter d_2 (Fig. 4b) is considered, this model representing, for example, a hair follicle or a blood vessel. Two modes of heating are considered. The first mode is a "rectangular EMR pulse" (Fig. 5a), and the second mode is a "rectangular temperature pulse" (Fig. 5b). In the case of the rectangular EMR pulse, the temperature of the heater rises during the EMR pulse, and reaches T_1 at the end of the pulse (Fig. 3b). In the case of the rectangular temperature pulse, the temperature of the heater is constant during the EMR pulse (Fig. 3a). For both modes of heating, the

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temperature of the heater is below the collapse temperature $T_{1\max}$, so absorbing properties of the of heater are not changed.

The sequence of thermal profiles during heating of the heater is depicted in Figs. 5a, 5b for the first mode and second mode of heating respectively, these profiles in the target and surround tissue being at different moments. The illustrative parameters for these profiles are $d_1 = 70 \mu\text{m}$, $d_2 = 210 \mu\text{m}$, collapse temperature $T_{1\max} = 100^\circ\text{C}$, corresponding to the boiling temperature of water, tissue damage temperature (T_2) = 70°C , associated with temperature of denaturation of proteins for pulsewidths in the range 10-1000 ms. The lower curve in both figures is the temperature profile at a time equal to the thermal relaxation time of the target (i.e. $\text{TRT} = d^2/16k$) where k is thermal diffusivity of the tissue; $k = 0.1 \text{ mm}^2/\text{s}$, $\text{TRT} = 27.5 \text{ ms}$ for the illustrative profile. At TRT, the temperature on the boundary of the target is significantly below the thermal damage temperature. The upper curve in both figures is the temperature profile at TDT when the target temperature reaches the damage temperature T_2 . At this moment, the target is damaged, but the surrounding tissue is not. For the illustrative profiles, $\text{TDT} = 1600 \text{ ms}$ for the rectangular EMR pulse, and $\text{TDT} = 360 \text{ ms}$ for the rectangular temperature pulse. From Figs. 5a, 5b, it is seen that (a) the ratio TDT/TRT is 58 and 14 times respectively; thus, for both modes, pulse width $\tau = \text{TDT}$ is significantly longer than TRT; and (b) at the end of TDT, the heated area is significantly larger than the damaged target. Thus, because of the spatial separation of highly pigmented areas and the target areas, the above technique differs from the classical case of selective photothermolysis in that the target is damaged not because of direct heating by absorption of EMR, but because of heat diffusion from the heater to the target. Fig. 5c is a cross-section through an illustrative hair shaft illustrating the relation of the profiles of Figs. 5a, 5b to the targeted hair follicle. In Fig. 5c, 26 is the hair shaft, 28 the inner root sheath, 30 the outer root sheath and 32 the location of stem cells (see also Fig. 1).

Heat diffusion strength depends on the geometry of the heater and the target. Three basic geometry examples, namely planes, cylinders and spheres (Fig. 4a-4c), are used to illustrate this. In all cases, a heater of size d_1 is assigned, located in the center of a target of size d_2 . A geometrical factor value $x = d_2/d_1$ is also defined. As above, T_1 is the maximum temperature of the pigmented area, and T_2 is the damage temperature of the target ($T_1 > T_2$). The thermal damage time of the target is:

$$\text{TDT} = \text{TRT} \times r(x, \Delta)$$

Here $r(x, \Delta)$ is a function of the geometrical factor x and a temperature factor Δ , where $\Delta = (T_2 - T_0) / (T_1 - T_0)$. T_0 is the temperature of the target and heater before irradiation. Normally T_0 is body temperature (37°C). Figures 6a-6c show the ratio $r(x, \Delta) = \text{TDT} / \text{TRT}$ as function of the geometrical factor x for two heating modes, the “rectangular EMR pulse” and the “rectangular temperature pulse”, Fig. 6a being for a plane target (Fig. 4a), Fig. 6b for a cylindrical target (Fig. 4b) and Fig. 6c being for a spherical target (Fig. 4c). Parameters for the calculations were $T_1 = 100^\circ\text{C}$, $T_2 = 70^\circ\text{C}$ and $T_0 = 36.6^\circ\text{C}$, resulting in $\Delta = 0.52$. Note that the ratio $r(x, \Delta)$ is not dependent on the size of the target or the thermal properties of the tissue. Several important conclusions follow from Figures 6a-6c:

- 1) The ratio TDT / TRT increases as the geometrical factor x is increased.
- 2) The value of this ratio is very different for plane, cylindrical and spherical targets. For plane targets, TDT is only a few times greater than the TRT , but for the same geometrical factor x , it is several dozen times greater than TDT for cylindrical and spherical targets.
- 3) For the same TDT / TRT , the size of the damaged area is smallest for a spherical target, next larger for a cylindrical target, and largest for a plane target. These results are to be expected because heat diffusion from plane, cylindrical and spherical targets is one, two and three dimensional respectively. The temperature profile is sharper and better localized for spherical heaters than for cylindrical heaters, and for cylindrical heaters it is sharper than for plane heaters. For the classical case of selective photothermolysis, the geometry of the target is not important because thermal damage takes place in the same area as the absorption of the EMR; however, it is important in the present case because, as a result of heat diffusion, thermal damage takes place in a different area than the absorption of EMR.

- 4) The ratio TDT / TRT depends highly on the heating mode. The rectangular EMR pulse mode (Fig. 3a, 4b) represents a more gradual heating mode because the temperature of the heater reaches the maximum T_1 at the end of the pulse (Fig. 4b). Ratio TDT / TRT is maximum for this mode. The rectangular temperature pulse mode (Fig. 3b, 4a) represents a more aggressive heating mode because the maximum temperature of the heater is found during the entire EMR pulse. The ratio TDT / TRT is minimum for rectangular temperature pulse mode. This mode requires a special shape

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for the EMR pulse with a high peak power at the beginning, and falling for the rest of the pulse (Fig. 3c) to maintain heat diffusion from the heater into surround tissue. Pulse power should be adjusted precisely to keep the temperature of the heater below its collapse temperature, $T_{1\max}$ (Fig. 3d). The power depends on the absorption coefficient of the heater, its size, and the attenuation of the EMR in the intervening tissue.

The ratio TDT/TRT also depends on the temperature factor $\Delta=(T_2-T_0)/(T_1-T_0)$. Fig. 7, which shows the influence of the maximum temperature of the heater T_1 for a cylindrical target, compares two cases having $T_1=100^\circ\text{C}$ ($\Delta=0.53$) and $T_1=200^\circ\text{C}$ ($\Delta=0.20$). TDT/TRT is close to one when the temperature of the heater is very high (for example 200°C). In biological tissue, such high temperatures can be expected with chromophores like carbon or melanin in the hair shaft.

Where the EMR pulse is square, with its amplitude and duration chosen to heat the heater just below T_1 and the target to T_2 , the three basic geometries of the target are used, the part with high absorption is located at the center of the target, d_1 is the size of the heater and d_2 is the total size of the target, and it is assumed that all tissue of the target surrounding the heater should be damaged by heating to above T_2 , TDT of the targets and input power density P and fluence F for rectangular EMR pulse follows from thermal diffusion theory and are given by formulas in Table 1:

Table 1

<u>N</u>	<u>Quantity</u>	<u>Notation</u> <u>[Dimen-</u> <u>sionality]</u>	<u>Approximate expression for a particular target geometry;</u>		
			<u>Planar</u>	<u>Cylindrical</u>	<u>Spherical</u>
<u>1</u>	<u>Thermal</u> <u>relaxation</u> <u>time of the</u> <u>heater</u>	τ_r [s]	$\tau_r = \frac{d_1^2}{8 \cdot k}$	$\tau_r = \frac{d_1^2}{16 \cdot k}$	$\tau_r = \frac{d_1^2}{24 \cdot k}$
<u>2</u>	<u>Thermal</u> <u>relaxation</u> <u>time of the</u> <u>target</u>	TRT [s]	$TRT = \frac{d_2^2}{8 \cdot k} =$ $= x^2 \cdot \tau_r$	$TRT = \frac{d_2^2}{16 \cdot k} =$ $= x^2 \cdot \tau_r$	$TRT = \frac{d_2^2}{24 \cdot k} =$ $= x^2 \cdot \tau_r$

<u>3</u>	<u>Thermal damage time</u>	TDT [s]	$TDT = \frac{TRT}{2 \cdot x^2} \cdot \left[\left(\frac{D - \Delta}{1 - \Delta} \right)^2 - 1 \right],$ $D = \exp(-x^2) + 1.8 \cdot x \cdot \text{erf}(x)$	$TDT = \frac{TRT}{x^2} \cdot \exp\left(\frac{D - 0.3 \cdot \Delta}{1 - \Delta}\right),$ $D = 0.6 + 2 \cdot \ln(x) - Ei(-1.4 \cdot x^2)$	$TDT = \begin{cases} 0.9 \cdot \frac{TRT}{x^2} \left[\left(\frac{1 - \Delta}{D - \Delta} \right)^2 - 1 \right], & D - \Delta > 0 \\ \infty, & D - \Delta \leq 0. \end{cases}$ $D = 0.7 \cdot \frac{\text{erf}(1.3 \cdot x)}{x}$
<u>4</u>	<u>Input power density</u>	P [W/cm ²]	$P = \frac{p \cdot c}{\mu_a q} \cdot \frac{1.1 \cdot x^2}{TRT} \cdot \frac{T_1 - T_0}{\sqrt{1 + 2.1 \cdot x^2 \cdot \frac{TDT}{TRT}} - 1}$	$P = \frac{p \cdot c}{\mu_a q} \cdot \frac{x^2}{TRT} \cdot \frac{T_1 - T_0}{\ln\left(1 + 1.4 \cdot x^2 \cdot \frac{TDT}{TRT}\right)}$	$P = \frac{p \cdot c}{\mu_a q} \cdot \frac{0.3 \cdot x^2}{TRT} \cdot \frac{T_1 - T_0}{1 - \frac{1}{\sqrt{1 + 1.2 \cdot x^2 \cdot \frac{TDT}{TRT}}}}$
<u>5</u>	<u>Input fluence</u>	F J/cm ²	F = P · TDT	F = P · TDT	F = P · TDT

The notations and the basic parameters of the problem are explained in Table 2:

Table 2

Variable	Dimensionality	Name	Assumptions and relations
K	cm ² s ⁻¹	Thermal diffusivity	Assumed to be the same all over the target
P	G cm ⁻³	Density	Assumed to be the same all over the target
C	J/(g°K)	Specific heat	Assumed to be the same all over the target
μ _a	cm ⁻¹	Tissue absorption coefficient	Assumed to be zero outside the heater
Q	a.u.	The ratio of radiance to the input power density	
d ₁	Cm	Thickness or diameter of the heater	
d ₂	Cm	Thickness or diameter of the target	d ₂ > d ₁
d ₃	Cm	Mean spacing between of the target	d ₃ > d ₂
T ₀	°C	Initial temperature of both the target and the surrounding tissue	T ₀ = 37° C
T _{1max}	°C	Temperature of heater absorption loss, collapse temperature	T _{1max} = 100° C - 250° C
T ₁	°C	Maximum temperature of the heater (absorber)	T ₂ < T ₁ ≤ T _{1max}
T ₂	°C	Temperature of irreversible damage of the tissue	T ₂ = 70° C
Δ	a.u.	Temperature factor, temperature ratio	Δ ≡ $\frac{T_2 - T_0}{T_1 - T_0} < 1$
X	a.u.	Geometrical factor, diameter ratio	x ≡ d ₂ / d ₁ > 1

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Fig. 6a-6c shows dependence of TDT on x. The conditions for the calculation of this figure are: $T_1=100^\circ\text{C}$ (boiling temperature of water), $T_2=70^\circ\text{C}$ (temperature of denaturation of protein for dwell time 0.1-1s) and $x=1$ to 4.

The value of the TDT can be up to 4 times longer than the TRT for plane targets, 120 times for cylindrical, and 500 times for spherical targets. Typical parameters of treatment for hair follicle and spider veins given by the formulas are provided in tables 3 and 4.

Table 3. Optimum pulsewidth for hair-follicle treatment

Hair type/ diameter	TRT of hair shaft, ms	TRT of hair follicle, ms	Halting hair shaft growth			Permanent hair-follicle destruction	
			TRT of hair matrix, ms	TDT of papilla blood vessel, ms		TDT of stem cell, ms	
				Rectangular temperature pulse	Rectangular light pulse	Rectangular temperature pulse	Rectangular light pulse
Fine/30 μ	0.6	5.4	<0.3	0.5	1.5	30	115
Medium coarse/70	3	27	<2	2.7	8.5	170	610
Large coarse/120 μ	9.6	87	<5	8	21	510	1800

10 Table 4. Optimum pulsewidth for treatment of spider veins

Diameter of vein, mm	Wall thickness, mm	TRT of blood volume, ms	TRT of vein, ms	TDT of vein and fluence F							
				$\lambda=577\text{nm}$				$\lambda=800$ or 1060nm			
				Rectangular temperature pulse		Rectangular light pulse		Rectangular temperature pulse		Rectangular light pulse	
				TDT, ms	F, J/cm^2	TDT, ms	F, J/cm^2	TDT, ms	F, J/cm^2	TDT, ms	F, J/cm^2
0.1	0.035	0.5	5	40	10	130	20	40	590	140	1090
0.25	0.08	4	35	150	6	515	15	150	335	610	615
0.5	0.12	35	135	215	4	740	6	215	115	1200	200
1	0.15	260	540	240	4	670	5	240	50	2400	90

Treatments for which the teachings of this invention are particularly adapted include wrinkle, hair and vascular lesion removal.

For wrinkle removal, since collagen provides the dermis with its basic structural integrity, it is generally believed that the removal of wrinkles in human skin can be accomplished by restructuring the dermal collagen. It is further understood that the process of collagen destruction, as well as collagen production, can be mediated by heating the collagen-containing portions of the dermis. This process of collagen

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destruction and collagen formation takes place over a rather broad temperature range (i.e., roughly 45-70 degrees Celsius). Increased collagen formation can also occur as a result of heating collagen/fibrocytes within the papillary dermis to a sublethal temperature above normal body temperature, this effecting/increasing fibrocyte metabolism. Furthermore, it is desirable that this lethal or sublethal heating take place primarily in the papillary dermis, the portion of the dermis closest to the dermal-epidermal (D-E) junction. Accordingly, this treatment is targeted at the upper portion of the dermis, from approximately 100 microns to approximately 1mm below the upper surface of the epidermis, and may be particularly targeted to the upper portion of this region. It should be noted that the process of wrinkle removal described above does not require the removal of the epidermis, usually referred to as "skin resurfacing", and is therefore less traumatic and more desirable as a cosmetic procedure. However, even in skin resurfacing, collagen restructuring is thought to be the fundamental process leading to a desirable wrinkle free result.

To heat the papillary dermis to the required temperature range, the melanin layer located at the D-E junction may serve as the chromophore for light absorption in the wavelength range approximately 400-1500 nm. While melanin is normally optimally absorbed in a wavelength band from approximately 500 nm to 1300 nm; this wavelength range is extended due to the added skin protection afforded the epidermis by the extra long pulse.

Using the discussion above as to the utility of using light pulses having long durations, preferably greater than 100 ms, to obtain maximum protection of the epidermis through parallel cooling, this wrinkle removal technique preferably requires pulse durations from 100 ms to 1 second or more. Depending on the skin type and other factors, times outside these ranges might also be employed. Through a combination of long pulse illumination of the dermis and contact cooling, an optimum temperature profile is produced in the papillary dermis for the restructuring of collagen, and accordingly wrinkle removal. Figure 8 shows the calculated temperature distribution for a cooled surface (10 degrees Celsius) and a laser pulse duration of one second at roughly 150 J/cm². With this curve, collagen remodeling extends about 200 microns into the papillary dermis, which should be sufficient for wrinkle removal. The target region of the papillary dermis mentioned above is shown to be in the range of 50-70 degrees Celsius.

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An explanation as to why the peak of the heating curve flattens out in the dermis in both Figs. 8 and 9 with increased pulse duration is as follows: Without cooling, a temperature distribution having its peak at the D-E junction (approx. 100 microns deep) is established. This distribution extends upward toward the skin surface and downward
5 into the dermis. With parallel cooling, heat is preferentially transferred to the skin surface, depressing the portion of the heat distribution curve closest to the surface. Since the portion of the curve toward the dermis is not controlled as strongly by the surface cooling, if at all, and is largely mediated by the vasculature in the dermis, the portion of the heating curve in the dermis is not as changed (reduced) as is the portion closest to the
10 surface of the skin. Fig. 9 illustrates this effect reasonably well at lower power (i.e., 50 J/cm²) which may be suitable for some applications such as hair removal. Fig. 8 illustrates the effect using three times the fluence, a regimen more suitable for wrinkle removal. This treatment may be concentrated in areas containing substantial wrinkles to further protect against skin damage.

15 An alternative technique for utilizing the teachings of this invention for wrinkle removal is to utilize a source operating in a wavelength band preferentially absorbed by water, for example a range of 0.95 micrometers to 1.9 micrometers and 2.1 to 2.4 micrometers, and otherwise irradiating and cooling as indicated above. Radiation in the wavelength band indicated, while preferentially absorbed by water, are not so strongly
20 absorbed that they cannot migrate at least several millimeters into the papillary dermis, heating water in the tissues of the papillary dermis sufficiently to raise the temperature of collagen in this area, resulting as indicated previously in the restructuring of such collagen.

There are a number of ways in which the teachings of this invention may be
25 utilized for hair removal. In particular, in practicing the teachings of this invention, melanin in the hair shaft may function as a chromophore as well as melanin in the lower portions of the follicle near/in the matrix and near the papilla. Each hair follicle has stem cells 32 which are, as shown in Figs. 1 and 5c, at the outer side of the outer root sheath
30 in an area at a depth of approximately 0.5 to 1.5 mm from the skin surface. This is sometimes referred to as the bulge area of the follicle. Since the stems cells in general do not contain a chromophore, these stem cells can usually be heated and destroyed only by heating chromophores adjacent thereto, and permitting heat from such chromophores to be transferred to the stem cells. The most convenient naturally-occurring chromophore

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adjacent to stem cells is the melanin in the hair shaft 26 itself. To destroy the stem cells, the hair shaft must be irradiated for a sufficient period of time for heat from the hair shaft to be transferred to the stem cells. For permanent hair-follicle damage, in accordance with current knowledge, it is necessary to damage stem cells that are located in the bulge area at the interface of the outer root sheath and the connective tissue sheath. One can also irreversibly damage a hair follicle at the level of the dermis by replacing it with connective tissue and blocked growth of new hair bulb. It is important that the hair shaft or other heater being utilized not be destroyed during this entire period (i.e., that the hair shaft or other heater – i.e., melanin in the matrix - does not become so hot that it becomes denatured and ceases to function as a chromophore). However, charring or carbonizing of the hair shaft or other heater is acceptable since this does not reduce absorption, and may in fact increase absorption. Further, since water vapor can interfere with the transfer of heat from the hair shaft or other heater to the stem cells or other target, it is desirable that the temperature of the tissue be kept below approximately 100-110°C, the temperature at which formation of water vapor may occur. Thus, the peak power of the optical radiation applied to the hair shaft/heater for this application should be low enough so that the hair shaft/heater does not heat to above approximately 100°C by the end of the treatment, and the heating should last for a time sufficient for the heat from the hair shaft/heater to be transferred to the outer sheath of the follicle where the stem cells are located and/or other appropriate target. As is discussed later, this time will vary somewhat with the size of the hair shaft and follicle. Where the applied radiation is at a wavelength selectively absorbed by fat, the sebaceous gland, which primarily contains fat or lipid, and which is also located at the depth of the bulge, may also function as a chromophore for the stem cells, either in addition to or instead of other chromophores discussed herein. With proper focusing, it may also be possible using wavelengths previously discussed to target water in the stem cells and/or tissue surrounding the stem cells and/or in/surrounding other appropriate target.

While the melanin in the hair shaft (and possibly in the stem cells for type IV patients), the lipid in the sebaceous gland and water in tissue surrounding the hair shaft (and possibly in the stem cells) are the only naturally-occurring chromophores adjacent to or in stem cells, it is also possible to introduce an artificial chromophore into this region for purposes of destroying the stem cells. Thus, a dye could be applied to the hair shaft, which dye migrates down the hair shaft at least to the level of the bulge, or an

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artificial chromophore such as carbon particles or magnetic particles of a selected optical quality can be applied to the skin and either naturally migrate into the follicle region or be forced into the follicle region using various techniques known in the art. It is also possible to epilate the hair shaft before applying the chromophore to facilitate its migration into the follicle region. With any of these techniques, the optical source would still be a relatively low peak power source of a wavelength appropriate for the chromophores being utilized, and would be applied for at least a sufficient duration so as to permit the heating of the chromophores to a temperature sufficient to damage or destroy the stem cells and/or other appropriate target, and for the heat from the chromophores to be transferred to the stem cells. Preferably, the chromophores are heated to temperature to prevent chromophore destruction and ablation (for example 100°C-300°C depending on the chromophore), or slightly above, so that with thermal losses as the heat migrates to the stem cells, the stem cells will still be heated to approximately 65°C-70°C, as required for their destruction. It is also preferable that temperatures above 65°C-70°C not reach much beyond the stem cells so as to avoid pronounced dermal damage. This is generally not a problem for regions of low density hair, but can be a problem for high density hair regions, where there can be accumulation of heat from adjacent follicles in dermal regions therebetween.

More specifically, since heat flux will leak out of the target, the heating area will be larger than the target. This increases the risk of overheating the tissue surrounding the target and thus the risk of nonselective damage. Very roughly, the fluence to produce nonselective bulk tissue damage F_{NS} is $(d_3/d_2)^n$ times greater than the fluence required to produce selective damage F_S , where d_2 and d_3 are the target size and distance between centers of the targets, and n is 1, 2 or 3 for planar, cylindrical and spherical targets, respectively. As a first approximation, F_{NS}/F_S is proportional to the ratio of target volume and tissue bulk volume and independent of pulsewidth, the risk of nonselective damage increasing in the following order: spherical, cylindrical and planar targets.

More precisely, for the ideal model of cylindrical targets with equal spacing (Fig. 12), Figs. 13a, 13b show the dependence of TDT, F_S and F_{NS} on density factor $y = d_3/d_2$ for a rectangular temperature pulse. As seen from Figs. 13a, 13b, TDT and F_S decrease in y beginning with $y = 5$. This effect is explained by the influence of heat fluxes from neighboring targets. But at the same time, the ratio F_{NS}/F_S starts dropping at $y = 5$. So

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for $y < 5$ the range of safe fluences is going to be very narrow and the risk of nonselective damage will increase.

More specifically, hair follicle heating to achieve permanent hair removal is usually accomplished through light absorption by hair shaft melanin, melanin near the follicle matrix and/or artificial dye. This dye could be applied to the hair shaft and/or follicle or in the space created by epilation of the hair shaft. The feature of the proposed method is that melanin or artificial dye heating continues until a certain thermal dose or temperature is reached and lasts as long as necessary for a protein denaturation zone (or thermal lesion) to extend to the outer sheath border where stem cells are located and/or another appropriate target. The thermal history and spatial profile of the temperature are primarily defined by two conditions. First, light absorption by the melanin or artificial dye, which should not decrease appreciably with heating. This means that there should be no drastic change such as melting or evaporation of the hair shaft or artificial dye, or photo-bleaching of the melanin or artificial dye, since this would cause follicle heating to stop or become ineffective. Second, the hair shaft or artificial dye and outer root sheath must not be heat-insulated from each other by, for example water vapor created by boiling of tissue water. The first condition is met if hair shaft temperature is not over one of the following: (a) 220-250°C, (b) a temperature of artificial dye photo-bleaching, (c) the temperature of dye evaporation. This latter temperature depends on the dye type. The second condition is satisfied if the hair shaft or artificial dye temperature does not exceed the tissue boiling temperature, which is about 100-110°C. The method thus requires that the temperature of the chromophores (melanin or artificial dye) be low enough to prevent its bleaching during light heating of a hair follicle. This temperature is preferably below the water boiling temperature (i.e., T_c or $T_{max}=100-110^\circ\text{C}$). To maintain the temperature of the chromophore at or below T_{max} , it is necessary to transport heat from the chromophore to the surrounding tissues (inner root sheath and outer root sheath) while adding heat to the chromophore. The power needed to ensure the heat production above, $P(t)$, depends on the diameter of the hair shaft. The formula for determining $P(t)$ appears in Table 1 for a rectangular pulse: The dependence of τ_0 on the diameter of the hair shaft is demonstrated in Figs 10a-10c. For areas having widely spaced hair, the dependence is described by formula (3), with τ_0 being approximately in the range 15ms – 5s (Fig. 10a). In the case of dense hair, because of

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the cumulative heat production by the hairs, τ_0 is less than 400ms (see Fig 10c). The above procedure of hair shaft heating ensures the total destruction of stem cells independent of the stage of hair growth. If hair is in the anagen stage and melanin is used for absorption, then stem cell damage is accompanied by matrix cell damage, since the melanin concentration and its absorption coefficient in the matrix is higher than that in the hair shaft. In this case, the matrix temperature exceeds T_{\max} . Through higher pulse duration, the structures of hair follicles thus become damaged. All these factors lead to a disruption of hair growth, and increased potential for permanent damage of the hair follicle, and thus permanent hair removal.

Another important effect is in the breakdown of the mechanical bond between the hair shaft and the dermis when thermal damage of the outer root sheath cell occurs. Owing to hair shaft temperature limitation during a treatment, the hair shaft remains intact and could be easily removed. Thus, the maintained hair shaft provides an objective criterion for hair follicle destruction; this criterion consists of mechanical removal of the hair shaft by gently pulling it out. The hair shaft can be removed with all or part of the follicle structure, including stem cells. This can be an additional mechanism of permanent hair removal. The hair shaft can be welded to the inner root sheath either with or without support of biological solder injected in the gap between hair shaft and inner root sheath.

A procedure for defining the parameters of the light treatment for this method might thus be:

1. Finding diameter d and absorption coefficient μ_a for a typical hair shaft. Both d and μ_a can be found by the use of standard methods. For example some hair (for statistical purposes) are mechanically removed and a diameter d is measured by means of a divider, and absorption μ_a at the wavelength (wavelengths) is measured by use of a spectrometer. The above wavelengths are those of the light source applied for hair removal. Both parameters can be defined by use of a contact microscope equipped with CCD-camera. If an artificial dye is used, μ_a is defined based on the concentration thereof.
2. Setting $T_{1\max}$ and following formulas in Table 1 to calculate the input flux.
3. Defining optimum pulse duration according to formula (3). For dense hair, a duration no more than 600 ms is chosen according to Fig. 10c.

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4. Choosing type of skin according to standard methods, for example by measurement of reflection coefficient of skin for different wavelengths.
5. Using the skin type and the pulse duration for the selected wavelength to find the accepted maximum flux and fluence (see Fig. 11).
- 5 6. Choosing the flux for treatment as the smallest value of (a) the flux defined on condition of keeping epidermis intact (see Fig. 9) and (b) the flux providing hair heating to temperature $T_{1\max}$ (see Eq. 1).

The above procedure may be carried out by applying the optical radiation locally or in a pattern with or without parallel cooling to achieve a spatial and temporal
10 temperature profile and thermal dose map, which may include using a compound sequence of interrupted pulsatile irradiations, or a quasi-continuous irradiation scheme, whereby the position of the light source is scanned or patterned over the area to be treated.

An alternative procedure would be to choose a test sample before treatment.
15 While hair shaving is not done, mechanical cutting is possible so long as the remaining length of the hair is sufficient to remove it.

Once minimum flux and pulse duration are chosen and the treatment is performed on the test sample, one can check if it is possible to pull the hair out with minimal force and that there has been no epidermal damage. If the hair does not come out and the
20 epidermis stays intact, the pulse duration is increased by, for example 50-100ms, and the steps are performed again, ranging up to a maximum pulse duration of about 5s. Then the flux is augmented and the treatment procedure is duplicated with a rise of the flux from minimum to maximum. If certain values of the flux and pulse duration result in the hair coming out under gentle pulling while the epidermis stays intact after the treatment,
25 then these parameters are suitable operational parameters for hair removal. If a certain value of flux and pulse duration result in damage of the epidermis but the hair pulls out with a great effort, then it may not be possible to remove hair from the skin of this patient by use of the invention. Experimental results achieved strongly suggest that it should be possible to treat all patients utilizing the teachings of this invention.

30 While for an individual hair shaft and hair follicle, the most appropriate set of exposure parameters can be chosen, as indicated above, the heterogenicity of hairs and hair follicles for a patient have to be considered in designing the most appropriate treatment of that patient. Different hair and hair follicles with similar properties can be

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grouped together. The more specific the differentiation of the group, the more appropriately each group can be treated. In general, division into a few group will allow treatment close to optimal treatment parameters. By applying multiple EMR pulses to the same area, each pulse's parameters optimized for a certain subset of hair follicles, allows more complete hair removal. These multiple pulses could either be applied in a short time interval over a single treatment or delivered during different treatment sessions. This technique effectively thins the hairs in the area, eliminating for example thinner hair first, thereby mitigating interaction problems in dense hair areas. This is because destruction of thinner hairs can occur before the TRT for the thicker hairs is reached.

A special mode of treatment is the delivery of multiple pulses with increasing flux from pulse to pulse. In this treatment mode, the thermal destruction of certain chromophores is intentional and can be described as "optical fuse". The calculations above demonstrate that with increasing flux, the threshold for hair shaft ablation is shifted to hairs containing less chromophore. If the outer root sheath cells are already destroyed by the preceding pulse, than the following pulse with a flux above the threshold for hair shaft ablation can remove the chromophore that is not needed anymore because this particular hair follicle is already destroyed. By removing the chromophore with increased flux, the EMR will only be absorbed by the remaining hair shafts with less chromophore. These hair follicles need a higher flux to generate sufficient temperature rise within the hair follicle. The maximum flux of this train of pulses is limited by the flux that is tolerated by the epidermis. This strategy of delivering a train of pulses, each targeting a different subset of hair follicles, and reduction in absorption of unnecessary EMR by removal of chromophores within already destroyed hair follicle is a novel treatment strategy. A higher ratio of damaged hair follicles within a treatment area can be expected with less danger of thermal damage, even for relatively dense hair areas. This is substantially different from a train of pulses each with the same flux and pulse duration, targeting the same subset of hair follicles. However, using parameters of EMR what are below the threshold of chromophore destruction will allow multiple treatment of a certain subset of hair follicles in order to get more complete destruction of this subset of hair follicles.

The invention may also be used for the elimination of unsightly vascular lesions such as leg veins. The strategy for eliminating leg veins using a laser or other EMR

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source is based on stopping the blood flow by either coagulating the blood, causing an occlusion in the vessel, or by applying external contact pressure capable of interrupting or impeding the flow of blood in the vessel. The degree to which this occlusion is necessary is determined by the irradiation parameters and the local tissue properties and depth of the treatment region. In the case of clot induction, it is preferable to substantially destroy the proximal endothelium of the blood vessel wall, which will reduce the production of the growth factors responsible for eliminating clots in the blood stream. Thus, to successfully treat the blood vessel, the inner lining of the vessel wall should be substantially destroyed;

The treatment of offending blood vessels can be augmented by mechanical or acoustical means known to those skilled in the art to achieve a reduction in blood flow or occlusion by pinching off the blood flow, or by coagulation of the blood, forming a blockage in the flow path. To ensure that enough hemoglobin and/or blood fluid chromophores remain near the treatment site, it is preferable to stop the flow of blood without ejecting the blood from the treatment region, such as might occur if a flat plate is pressed against the skin with sufficient pressure. For permanent sealing of the blood vessel, tissue welding may be induced, preferably upon heating the vessel to the degree of destroying the epithelial layer, and by applying external pressure to press the now exposed and heated collagen layers together, allowing them to form a tissue weld bond.

Using the inventive concept of heating chromophores, but not destroying the chromophores, a process can be performed whereby the hemoglobin, water in the blood and/or the blood fluid act as the chromophores, converting, the applied radiation light into heat. As long as the chromophores used in the treatments (e.g. melanin, water, hemoglobin, blood fluid) have a higher threshold for photo-thermal damage than the tissues in the surrounding treatment volume (e.g. stem cells, collagen, epithelial vessel walls) the concept presented herein can be applied to use bulk heating originating from the light-absorbing chromophores to treat the surrounding area, thus defining a prescribed treatment volume outside of which no permanent damage will occur, even if the treatment times exceed the thermal relaxation time for the tissues in question. While radiation used for blood coagulation has generally been in the 540 nm to 580 nm range in the prior art, less epidermal heating occurs at longer wavelengths, for example 810 nm available from a diode laser. By using a pulse duration which is longer than the thermal diffusion time for the vessel, a tissue volume larger than the blood vessel is heated. This

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bulk heating of the blood vessel and surrounding tissue results in the uniform destruction of the vessel endothelium, decreasing growth factor and perhaps ensuring the permanent blockage, and therefore elimination, of the blood vessel.

The basic idea of this application, the use of long pulse light sources having low
5 peak power, suggests using non-laser devices to supply light energy for performing dermatological/cosmetic procedures. It appears that concern as to scarring with long pulse optical treatments, and in particular with pulses having a duration longer than the thermal relaxation time of the target component, may not be a serious restriction, since in early clinical studies, the pain threshold for the patient seems to be reached before any
10 serious dermal damage occurs, which can lead to scarring. Therefore, so long as the treatment is terminated when the patient reports pain, the risk of scarring is very limited. This procedure can permit safe pulse durations for a given source to be empirically determined. Fig. 11 shows one set of illustrative curves. Further, low power, long pulse treatments result in the slow heating of tissue beyond the target component, which is
15 moderated by blood flow in the region to maintain tissue temperature in such a region below its damage threshold, even for very long pulses.

Since the procedure of this invention does not destroy the chromophores, it can be expected that a weak light source, used over an extended period of time, will be effective in tissue modification/damage/destruction. This means that light sources from
20 incandescent bulbs (home device) to halogen lamps (home device) to the sun are potential light sources for dermatologic/cosmetic procedures. Dyes which can act as surrogate chromophores in transforming light to heat energy, for example carbon or other black chromophores for a wide spectrum light source, and/or known frequency shifting or filtering techniques can be used for selected procedures, as required.

25 While in the discussion above, the target has generally been damaged or destroyed by being heated to a temperature well above normal body temperature, it is also possible to achieve selective target damage or other therapeutic effect by heating the target to a temperature only several degrees above body temperature for a prolonged period to achieve localized hyperthermia. Such heating may be achieved by either direct
30 heating of a target containing a suitable chromophore or by indirect heating of the target by heat diffusion from an absorbing chromophore, as described above. Pulse durations of more than 20 seconds might be appropriate for this type of treatment, and exposure or

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treatment times substantially greater, perhaps even in the range of minutes to hours, may be necessary in some instances.

For example, postfebrile temporary alopecia (i.e., hair loss at elevated temperature, for example when a patient has a high fever), is a well-known phenomenon.

5 The critical fever temperature that can cause temporary hair loss is approximately 39°C. This indicates a susceptibility of hair follicle cells to hyperthermia. While heating the entire body nonselectively in order to achieve hair removal may not be practical and could cause unwanted side effects, a treatment procedure where temperature in a range of a few degrees above body temperature are achieved close to the hair follicles in order to
10 cause hair loss is an option. In order to achieve hair loss with these relatively low temperature increases, exposure in the range of minutes to hours is probably necessary. This would result in the temperature distribution within the tissue being close to a steady state profile. The low peak power/long pulse duration teachings of this invention can be used to calculate appropriate power and pulse duration for achieving hyperthermia
15 treatments. However, with prolonged exposure, the body performs compensating mechanisms, like increased blood flow and sweating, which have to be considered to calculate appropriate parameters. It therefore may be more accurate to empirically determine appropriate parameters using for example feedback mechanisms. For example, the onset of pain or the monitoring of skin temperature either at or close to the
20 skin surface might be utilized to control power and duration with this regimen.

A hyperthermia regimen may also be employed by introducing an artificial chromophore into the middle part of the hair shaft, a very low power EMR source being utilized in this case in combination with very long exposure times. Hyperthermia-type treatment might also be utilized for skin resurfacing with melanin in the epidermis being
25 used to induce hyperthermia of the papillary dermis.

Long pulse heating of a hair shaft or hair follicle can also enhance adjuvant therapies, for example PDP or other photo-excited processes for hair removal. The increased temperature in the long pulse regimen can enhance susceptibility to photochemical induced damage.

30 It is also known that certain biological tissue responses are triggered by a prolonged exposure of tissue to elevated heat, and that some of these biological responses may enhance the susceptibility of the tissue to further tissue damage. Thus, heat exposure during an initial treatment can result in perifollicular edema which

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decreases perifollicular capillary blood flow. This reduces the removal of heat due to heat convection, permitting outermost structures of the hair follicle to be more effectively heated during a subsequent long pulse treatment. Other useful biological tissue responses may also occur.

5 Finally, while the discussion above has been primarily described with respect to various dermatology treatments, the low peak power/long pulse duration regimens of this invention are by no means limited to the field of dermatology and may be advantageously employed in other EMR therapies. For example, such a regimen might be useful for treating ophthalmic diseases such as macular degeneration where great care
10 must be exercised to achieve therapeutic results in the desired area of the eye without causing damage to adjacent areas such as the optic nerve. Lower energy radiation delivered over a significantly longer duration might permit the desired therapeutic effects to be achieved while reducing the danger of blindness in the eye if an undesired area is accidentally momentarily irradiated.

15 Attached as an Exhibit to this application is an unpublished article, the contents of which are not to be printed.

 While the invention has been discussed above with respect to preferred embodiments, it is apparent that these embodiments are for purposes of illustration only, and that variations thereon will be apparent to ones skilled in the art while still remaining
20 within the spirit and scope of the invention, which is to be defined only by the appended claims.

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CLAIMS

1. A method for performing a medical procedure by applying electromagnetic radiation (EMR) to a treatment area of a patient's body which may contain at least one chromophore, such radiation being of at least one wavelength absorbed by said
5 chromophore, having a power profile with an average power (P_a) and peak power (P_p), (P_p) being insufficient to cause a change in the at least one chromophore which results in significant loss of absorption, and having a duration long enough for sufficient energy for the procedure to be applied at said power profile to the treatment area.
- 10 2. A method as claimed in claim 1, wherein said target area has a thermal relaxation time (TRT), and wherein said duration is greater than said TRT.
3. A method as claimed in claim 2, wherein said duration is substantially greater than the TRT.
- 15 4. A method as claimed in claim 1, wherein said peak power is less than 500 watts.
5. A method as claimed in claim 1, wherein said EMR is continuous wave, and wherein peak power and average power for said radiation over said duration are roughly
20 the same.
6. A method as claimed in claim 1, where said chromophore is heated to a temperature which is no more than approximately 110°C so as to avoid vaporization of tissue.
- 25 7. A method as claimed in claim 1, wherein said procedure is hair removal, wherein said chromophore is melanin of a hair shaft in a hair follicle, and wherein said duration is sufficient for sufficient heat from said hair shaft to reach an outer root sheath of said follicle to damage stem cells located thereat.
- 30 8. A method as claimed in claim 1, wherein said procedure is hair removal, wherein said chromophore includes a heater in at least one follicle located in said target area, and

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wherein said power profile and duration are sufficient to at least damage at least one critical element of the follicle.

9. A method as claimed in claim 1, wherein said procedure is wrinkle removal,
5 wherein said chromophore is melanin at the dermis-epidermis (DE) junction, and
wherein said power profile and duration are sufficient to heat collagen in the patient
papillary dermis sufficiently to restructure such collagen.
10. A method as claimed in claim 1, wherein said procedure is destructions of
10 vascular lesions, wherein said chromophore is blood in the vascular lesion, and wherein
said duration is sufficiently longer, at said power profile, than the thermal diffusion time
of the vessel for bulk heating of the vessel.
11. A method as claimed in claim 1, wherein said wavelength is absorbed by melanin
15 in the patient's epidermis, including at the dermis-epidermis (DE) junction, and wherein
said power profile and duration are such that heat generated as a result of EMR
absorption in epidermal melanin can migrate to the skin surface and be removed
concurrent with irradiation, thereby controlling temperature increase in the epidermis
during irradiation.
- 20 12. A method as claimed in claim 1, including reapplying said EMR to said treatment
area with a power profile and duration selected to one of retarget the same chromophore
in the treatment area and target a different chromophore in the target area.
- 25 13. Apparatus for performing a medical procedure on a treatment area of a patient's
body containing at least one chromophore including a source of electromagnetic
radiation (EMR) of at least one wavelength absorbed by said chromophore, an applicator
applying the EMR to a treatment area of a patient's body, and controls causing the EMR
applied to the target area to have a power profile with an average power (P_a) and peak
30 power (P_p), (P_p) being insufficient to cause a change in the at least one chromophore
which results in significant loss of absorption, and to have a duration long enough for
sufficient energy for the treatment to be applied at said power profile to the treatment
area.

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14. Apparatus as claimed in claim 13, wherein said target area has a thermal relaxation time (TRT), and wherein said duration is greater than said TRT.
- 5 15. Apparatus as claimed in claim 14, wherein said duration is substantially greater than the TRT.
16. Apparatus as claimed in claim 13, wherein said peak power is less than 500 watts.
- 10 17. Apparatus as claimed in claim 13, wherein said EMR is continuous wave, and wherein peak power and average power for said radiation over said duration are roughly the same.
- 15 18. Apparatus as claimed in claim 13, wherein said chromophore is heated to temperature which is no more than approximately 110°C so as to avoid vaporization of tissue.
19. Apparatus as claimed in claim 13, wherein said procedure is hair removal,
- 20 wherein said chromophore is a hair shaft in a hair follicle, and wherein said duration is sufficient for sufficient heat from said hair shaft to reach an outer root sheath of said follicle to damage stem cells located thereat.
20. Apparatus as claimed in claim 13, wherein said procedure is hair removal,
- 25 wherein said chromophore includes a heater in at least one follicle located in said target area, and wherein said power profile and duration are sufficient to at least damage at least one critical element of the follicle.
21. Apparatus as claimed in claim 13, wherein said procedure is wrinkle removal,
- 30 wherein said chromophore is melanin at the DE junction, and wherein said power profile and duration are sufficient to heat collagen in the papillary dermis sufficiently to restructure such collagen.

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22. Apparatus as claimed in claim 13, wherein said procedure is destructions of vascular lesions, wherein said chromophore is blood in the vascular lesion, and wherein said duration is sufficiently longer at said power profile than the thermal diffusion time of the lesion for bulk heating of the lesion.

5

23. Apparatus as claimed in claim 13, wherein said wavelength is absorbed by melanin in the patient's epidermis, including at the dermis-epidermis (DE) junction, and wherein said power profile and duration are such that heat generated as a result of EMR absorption in epidermal melanin can migrate to the skin surface and be removed
10 concurrent with irradiation, thereby controlling temperature increase in the epidermis during irradiation.

24. Apparatus as claimed in claim 23 including a mechanism which actively cools at least the portion of said skin surface over the treatment area at least substantially
15 concurrent with application of EMR to said treatment area.

25. Apparatus as claimed in claim 13 including a detector for at least one patient physiological condition, said controls being responsive to said detector for controlling at least one of EMR power profile and duration.

20

26. Apparatus as claimed in claim 13, wherein said radiation source is a low peak power laser source.

27. Apparatus as claimed in claim 13, wherein said radiation source is a low peak
25 power non-coherent light source.

28. A method for performing a medical procedure on a target area of a patient's body, said target area having a thermal relaxation time (TRT) and including a highly absorbent heater portion, the method including applying electromagnetic radiation
30 (EMR) to at least the heater portion of said target area of at least one wavelength highly absorbed by said heater portion, of a duration close to or greater than said thermal relaxation time, and having a power profile sufficient over said duration to accomplish said medical procedure.

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29. A method as claimed in claim 28 wherein said duration is significantly greater than TRT.

5 30. A method as claimed in claim 28, wherein said target area has a thermal damage time (TDT) which is the time required at said power profile for said entire target area to reach a thermal destruction temperature; and wherein the duration of said radiation is substantially equal to said TDT.

10 31. A method as claimed in claim 30, wherein said duration (t) for the EMR is equal (TDT- δ), where δ is roughly the propagation time for heat from the heater portion to a non-heater portion of the target furthest from the heater.

15 32. A method as claimed in claim 30, wherein $TDT = TRT \cdot r(x, \Delta)$, where x is a geometrical factor and Δ is a temperature factor.

33. A method as claimed in claim 32, wherein $x = d_2/d_1$ where d_1 = size of heater portion and d_2 = size of total target, and wherein $\Delta = (T_2 - T_0)/(T_1 - T_0)$ where T_0 is target/heater temperature before irradiation, T_1 is the heater temperature and T_2 is the temperature at which irreversible thermal damage of the target area generally occurs.

20

34. A method as claimed in claim 30, wherein said target is a hair follicle, and said heater portion includes a pigmented hair shaft in said follicle, TDT being the time required for heat to the thermal destruction temperature to reach an outer sheath of the follicle.

25

35. A method as claimed in claim 30, wherein said target is a blood vessel, said heater portion including blood in the vessel, and TDT being the time required for heat to the thermal destruction temperature to reach through walls of the blood vessel in a target area.

30

36. A method as claimed in claim 30, wherein said target is collagen in the patient papillary dermis, said heater portion being melanin at the dermal-epidermal (DE)

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junction, and TDT being the time required for heat at the thermal destruction temperature to reach a desired depth in said papillary dermis.

37. A method as claimed in claim 30, wherein said power profile is such that at TDT,
5 the entire target area is at a temperature of at least the thermal destruction temperature, but substantially no tissue outside the target area is at or above the thermal destruction temperature.

38. A method as claimed in claim 28, including cooling the patient's skin in an area
10 over said target area to remove heat from the patient's epidermis.

39. Apparatus for performing a medical procedure on a target area of a patient's body, said target area having a thermal relaxation time (TRT) and including a highly absorbent heater portion, including: a source of electromagnetic radiation (EMR) of at
15 least one wavelength highly absorbed by said heater portion; an applicator for applying EMR from said source to at least the heater portion of said target area; and controls for operating at least one of said source and said applicator to apply EMR to said target area for a duration significantly greater than said thermal relaxation time and with a power profile sufficient over said duration to accomplish said medical procedure.

20

40. Apparatus as claimed in claim 39, wherein said target has a thermal damage time (TDT) which is the time required at said power profile for said entire target to reach a thermal destruction temperature; and wherein the duration of said radiation applied to said target area is substantially equal to said TDT.

25

41. Apparatus as claimed in claim 40, wherein said duration (t) during which EMR is applied to the target is equal (TDT- δ), where δ is roughly the propagation time for heat from the heater portion to a non-heater portion of the target furthest from the heater portion.

30

42. Apparatus as claimed in claim 40, wherein $TDT = TRT \cdot r(x, \Delta)$, where x is a geometrical factor and Δ is a temperature factor.

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43. Apparatus as claimed in claim 42, wherein $x = d_2/d_1$ where d_1 = size of heater portion and d_2 = size of total target, and wherein $\Delta = (T_2 - T_0)/(T_1 - T_0)$ where T_0 is target/heater temperature before irradiation, T_1 is the heater temperature and T_2 is the temperature at which irreversible thermal damage of the target area generally occurs.

5

44. Apparatus as claimed in claim 39, including a mechanism operative at least during application of EMR to said target area which cools the patient's skin in an area over said target area.

10 45. A method for performing a medical procedure on a target area of a patient's body, said target area including a highly absorbent heater portion, the method including applying electromagnetic radiation EMR to at least the heater portion of said target area of at least one wavelength highly absorbed by said heater portion, having a power profile which heats said heater portion to a temperature T which is greater than a thermal
15 damage temperature for at least a portion of the target area to be damaged, but less than a collapse temperature at which said heater portion undergoes a change which results in significant loss of absorption at said at least one wavelength, and having a duration sufficient with said power profile to accomplish said medical procedure.

20 46. A method as claimed in claim 45, wherein said target has a thermal damage time (TDT) which is the time required for said entire target to reach said thermal destruction temperature at said power profile, and wherein said duration is substantially equal to TDT.

25 47. A method as claimed in claim 45, wherein at said collapse temperature, said heater portion undergoes a phase transition causing at least one of bleaching, melting, boiling, bubble formation and other destructive process.

30 48. A method as claimed in claim 45, wherein said heater portion is a naturally occurring chromophore in the patient's body.

49. A method as claimed in claim 45, wherein said heater portion is at least in part an artificial chromophore introduced to said target area.

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50. A method as claimed in claim 45, wherein said medical procedure is hair removal, wherein said heater portion includes a hair shaft in a hair follicle which hair shaft has a collapse temperature of up to 250°C, and wherein said duration is 0.5 ms to 20 sec.
51. A method as claimed in claim 45, wherein said medical procedure is removal of vascular lesions, and wherein said duration is 0.5 ms to 20 sec.
52. A method as claimed in claim 45, wherein said medical procedure is collagen remodeling and wherein said duration is 100 ms to 20 sec.
53. A method as claimed in claim 45 including repeating said applying step at least one additional time to further damage at least selected portions of said target area.
54. A method as claimed in claim 53 wherein heaters in a target area are not uniform and therefore have different collapse temperatures, wherein, during a selected performance of said applying step, portions of said target area heated by a heater are treated without exceeding the thermal collapse temperature of the heater, and wherein, during subsequent performance of the applying step, the thermal collapse temperature for said heaters is exceeded without exceeding the thermal collapse temperature of heaters heating portions of the target area for which treatment is not completed.
55. A method as claimed in claim 45 wherein said power profile is such that the temperature of said heater is substantially constant for said duration.
56. A method as claimed in claim 45 wherein said power profile and duration are such as to result in hyperthermia in said target area to accomplish said medical procedure.
57. Apparatus for performing a medical procedure on a target area of a patient's body, said target area including a highly absorbent heater portion, including: a source of electromagnetic radiation (EMR) of at least one wavelength highly absorbed by said

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heater portion, an applicator applying said radiation to at least the heater portion of said target area, and controls for at least one of said source and said applicator to cause said EMR applied to the target area to have an power profile which heats said heater to a temperature T which is greater than a thermal damage temperature for at least a portion of the target to be damaged, but less than a collapse temperature at which said heater portion undergoes a change which results in significant loss of absorption at said at least one wavelength, and of a duration sufficient with said power profile to accomplish said dermatology procedure.

58. Apparatus as claimed in claim 57, wherein said target has a thermal damage time (TDT) which is required for said entire target to reach said thermal destruction temperature at said power profile, and wherein said duration is substantially equal to TDT.

59. Apparatus as claimed in claim 57, wherein said EMR source is an optical radiation source.

60. Apparatus as claimed in claim 57, wherein said power profile is such the temperature of said heater is substantially constant for said duration.

61. A method for performing a medical procedure on a target area of a patient's body, said target area including at least one absorbent heater portion and at least one non-heater portion having weak absorption to no absorption, said at least one non-heater portion being spaced to varying degrees from said at least one heater portion, the method including applying electromagnetic radiation (EMR) to at least heater portions of said target area of at least one wavelength highly absorbed by said heater portions, having a power profile which heats said heater portions to a temperature T which is greater than a thermal damage temperature for the portions of the target area to be damaged, but less than the collapse temperature at which said heater portions undergo a change which results in significant loss of absorption at said at least one wavelength, and of a duration sufficient with said energy profile to permit the heating of substantially all of said target area from said heater portions to a temperature sufficient to accomplish said medical procedure.

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62. A method as claimed in claim 61, wherein the temperature to which substantially all of said target area is heated is at least equal to a thermal destruction temperature for said target area.

5 63. A method as claimed in claim 61, wherein there are a plurality of target areas in an aperture being irradiated by said EMR, each of said areas being of a size d_2 , and centers of said target areas being spaced by a distance d_3 , and wherein the ratio of fluence F_{NS} at which damage outside a target area occurs to fluence F_S at which selective damage of a complete target area occurs is $F_{NS}/F_S = (d_3/d_2)^n$, wherein n is dependent on
10 target shape.

64. A method for performing a medical procedure by applying electromagnetic radiation (EMR) of appropriate wavelength to a treatment area of a patient's body, such wavelength being absorbed by melanin in the patient's epidermis, including at the
15 dermis-epidermis (DE) junction, and wherein said EMR has a power profile and duration which are sufficient to effect the medical procedure and are such that heat generated as a result of EMR absorption in epidermal melanin can migrate to the skin surface and be removed concurrent with irradiation, thereby controlling temperature increase in the epidermis during irradiation.

20

65. A method as claimed in claim 64, including actively cooling said skin surface at least during said duration.

66. Apparatus for performing a medical procedure on a patient's body including: a
25 source of electromagnetic radiation (EMR) of a wavelength appropriate for said procedure, said wavelength being absorbed by melanin in the patient's epidermis, including at the dermis-epidermis (DE) junction, an applicator for applying the EMR to a treatment area of the patient's body, and controls for at least one of said source and said applicator which cause said EMR to be applied with a power profile and a duration to
30 effect said medical procedure and which are such that heat generated as a result of EMR absorption in epidermal melanin can migrate to the skin surface and be removed concurrent with irradiation, thereby controlling temperature increase in the epidermis during irradiation.

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67. Apparatus as claimed in claim 66, wherein said source is a source of optical radiation.

5 68. Apparatus as claimed in claim 66, including a mechanism for actively cooling said skin surface at least during said EMR duration, facilitating the removal of heat therefrom.

69. A method for performing a medical procedure on a target area of a patient's
10 body, said target area including a highly absorbent heater portion, the method including applying electromagnetic radiation (EMR) to at least the heater portion of said target area of at least one wavelength highly absorbed by said heater portion, having a power profile which heats said heat portion to a temperature T, said applying step having a duration sufficient with said power profile to accomplish said medical procedure, and said power
15 profile resulting in the temperature T of said heater being substantially constant during said durations.

70. A method as claimed in claim 69, wherein said power profile results in optical power decreasing substantially exponentially during said duration.

20

71. Apparatus for performing a medical procedure on a target area of a patient's body, said target area including a highly absorbent heater portion, including:

a source of electromagnetic radiation (EMR) of at least one wavelength highly absorbed by said heater portion, an applicator applying said radiation to at least the
25 heater portion of said target area, and controls for at least one of said source and said applicator to cause said EMR applied to the target area to have an power profile which heats said heater to a temperature T, said EMR having a duration sufficient with said power profile to accomplish said medical procedure, and said power profile resulting in the temperature T of said heater being substantially constant during said durations.

30

72. An apparatus as claimed in claim 71, wherein said power profile results in optical power decreasing substantially exponentially during said duration.

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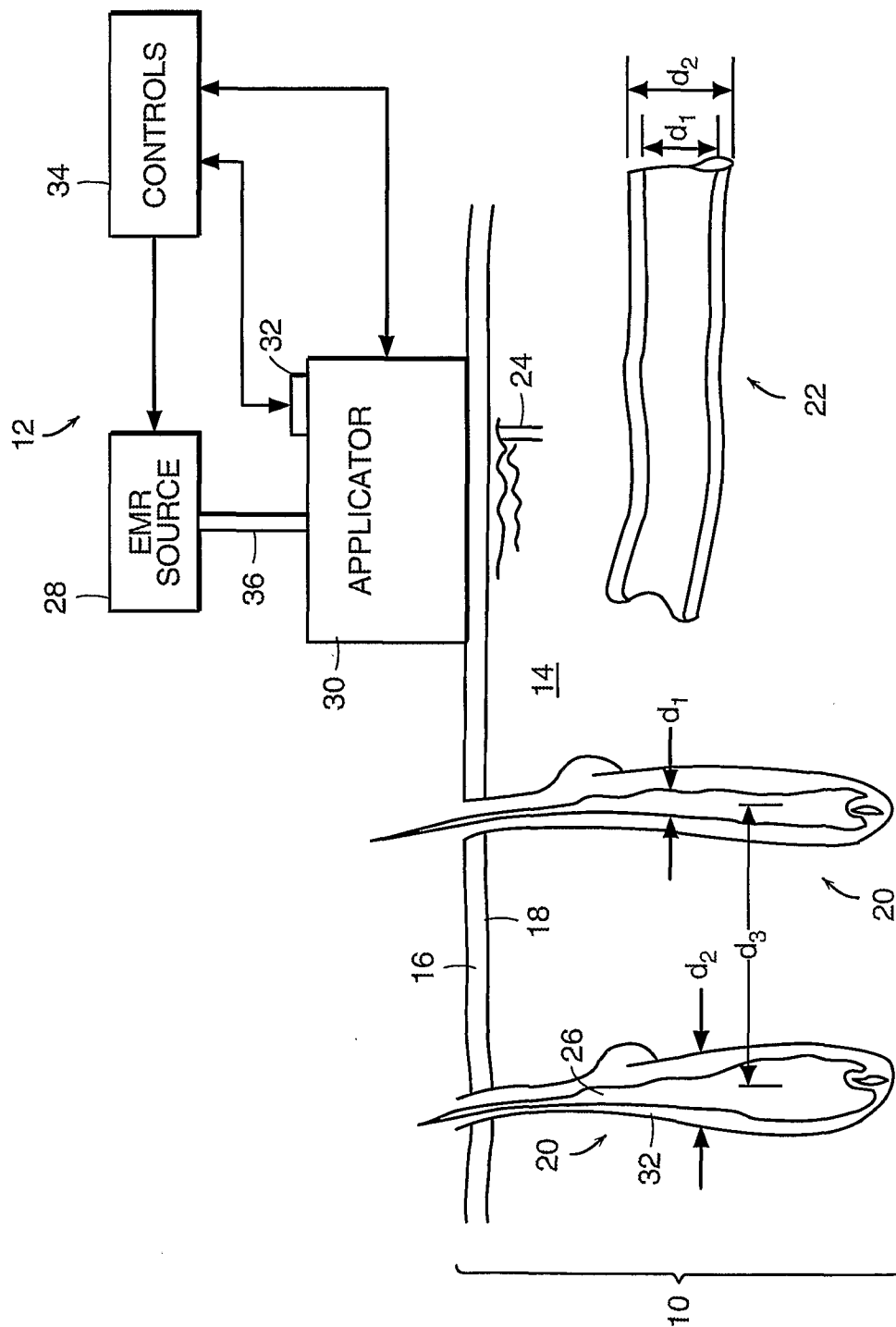


FIG. 1

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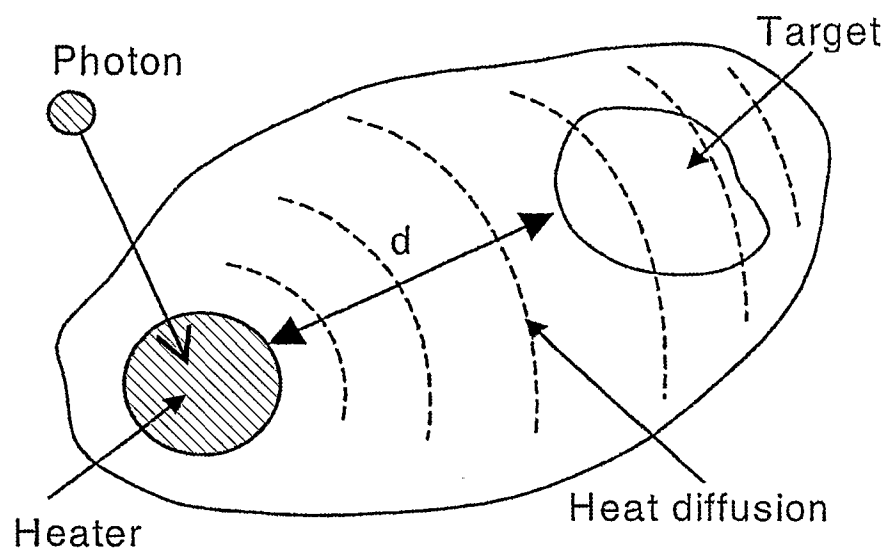


FIG. 2

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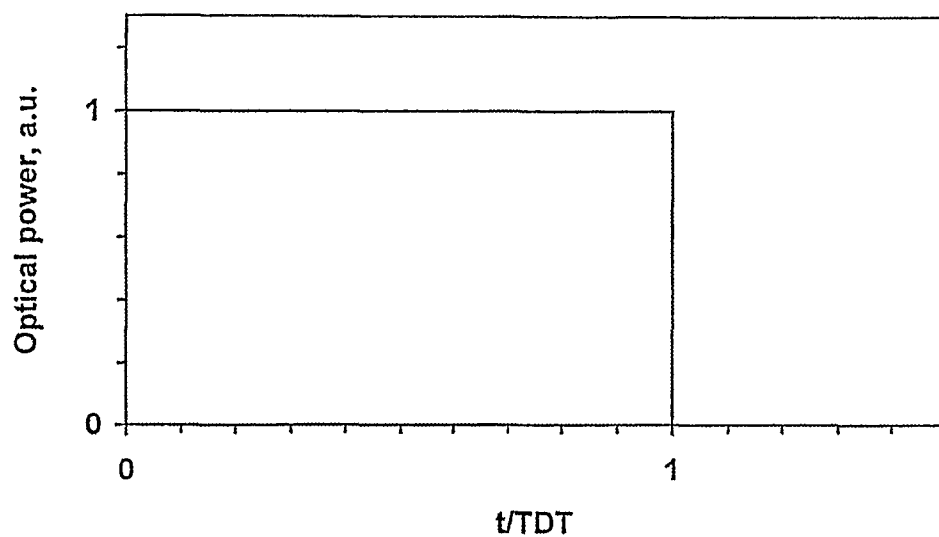


FIG. 3a

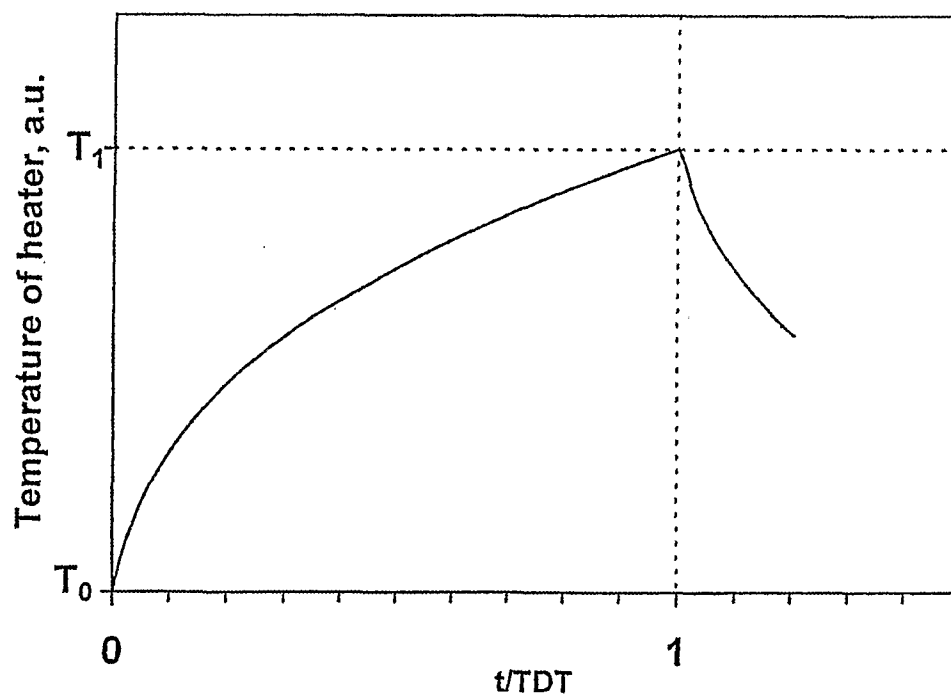


FIG. 3b

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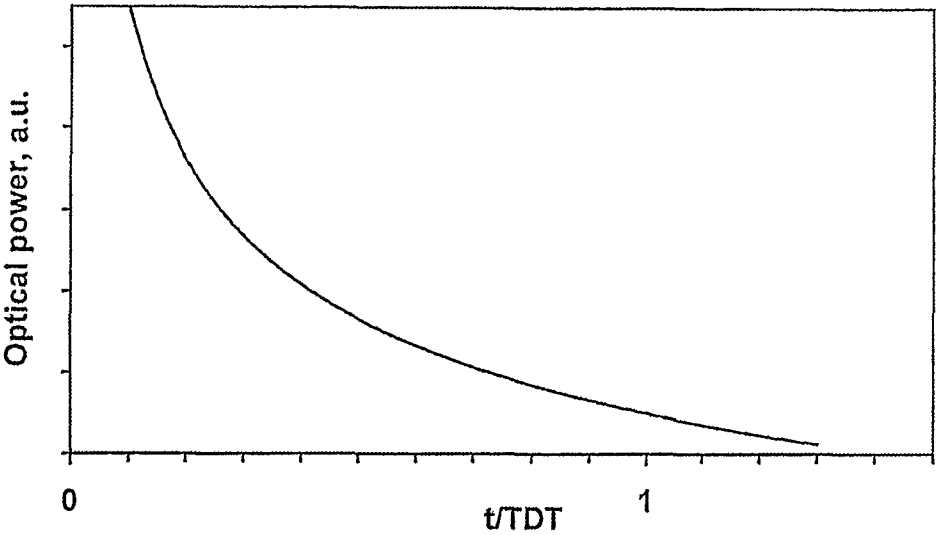


FIG. 3c

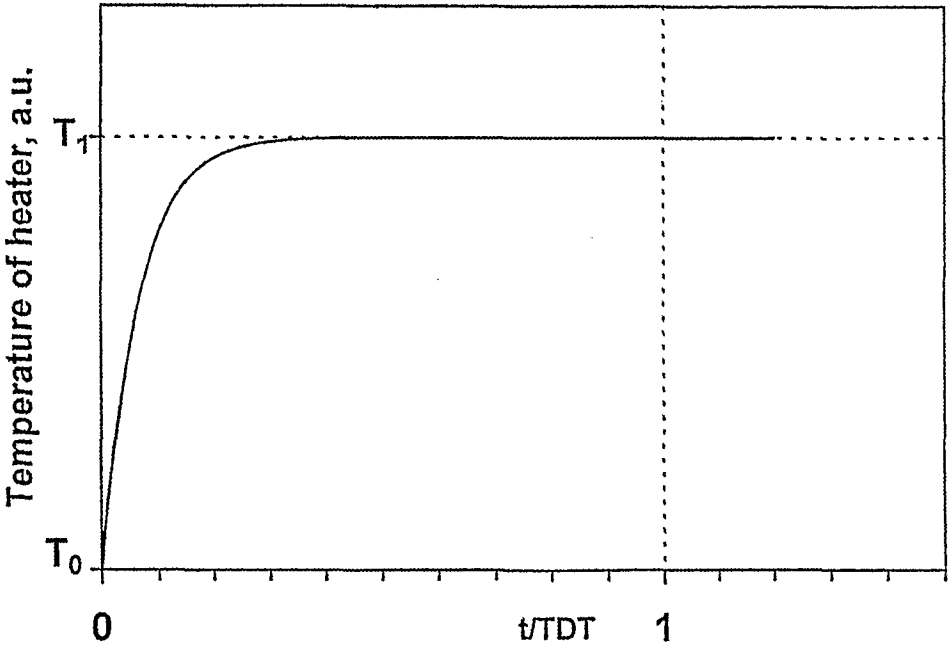


FIG. 3d

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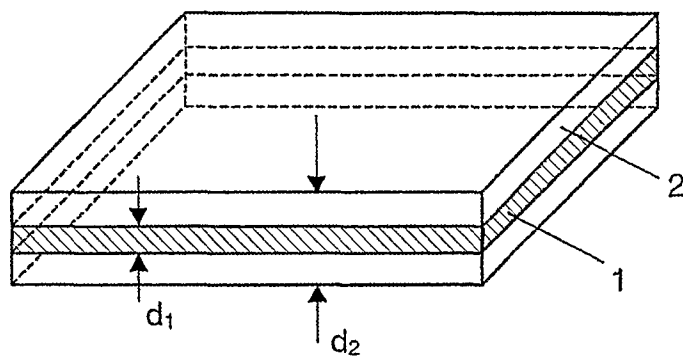


FIG. 4a

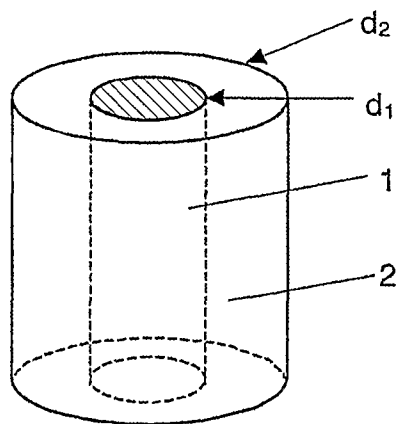


FIG. 4b

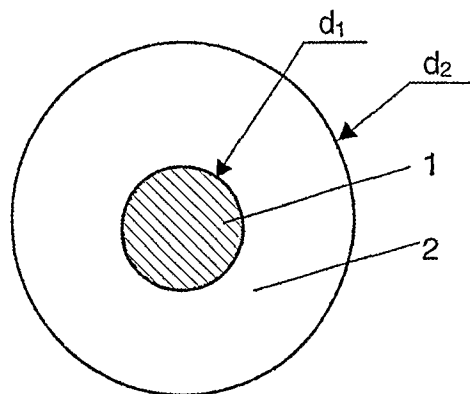


FIG. 4c

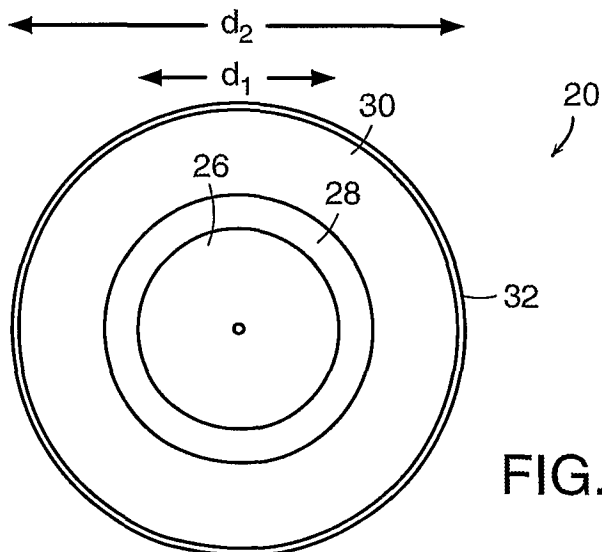
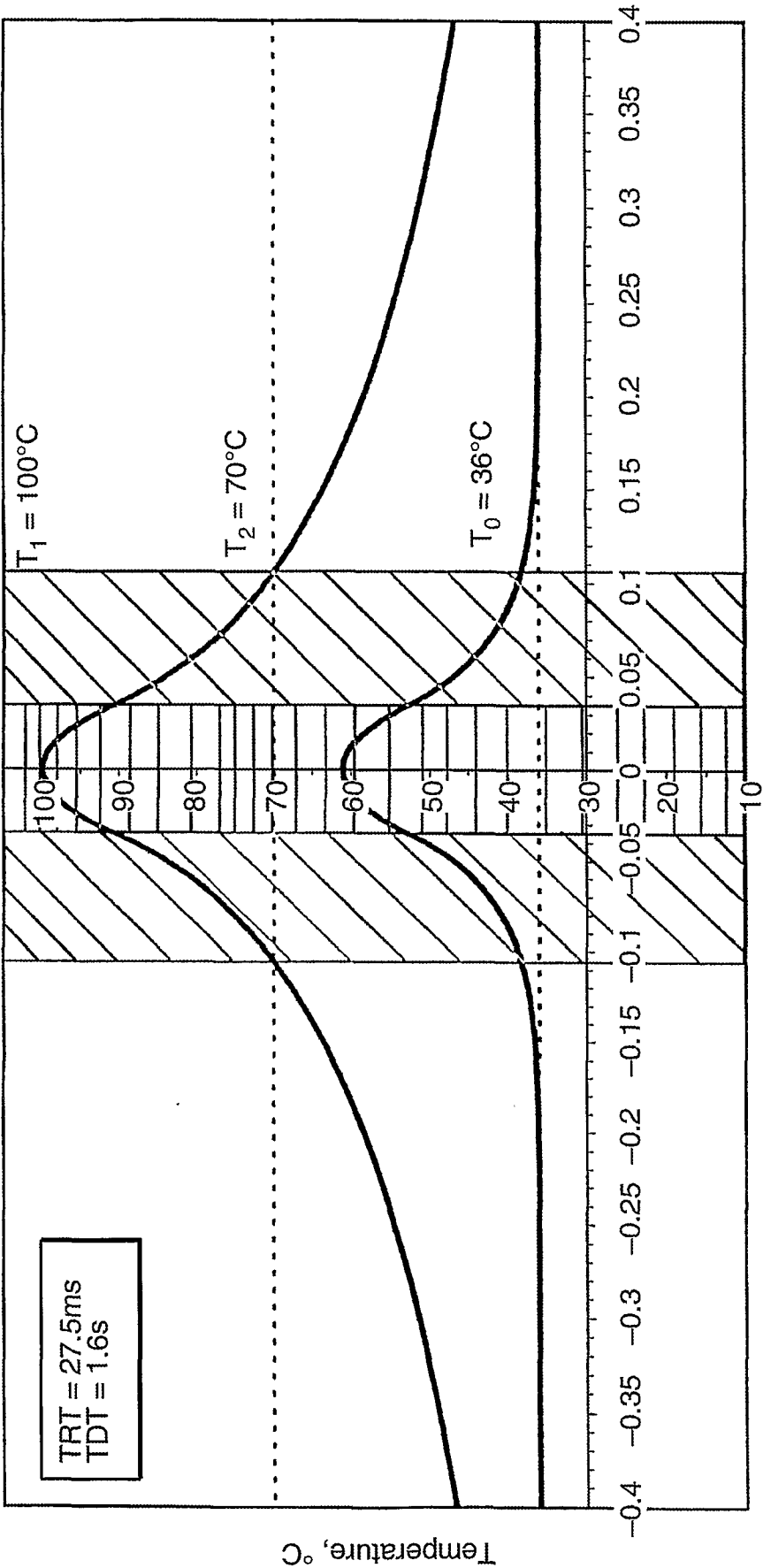


FIG. 5c

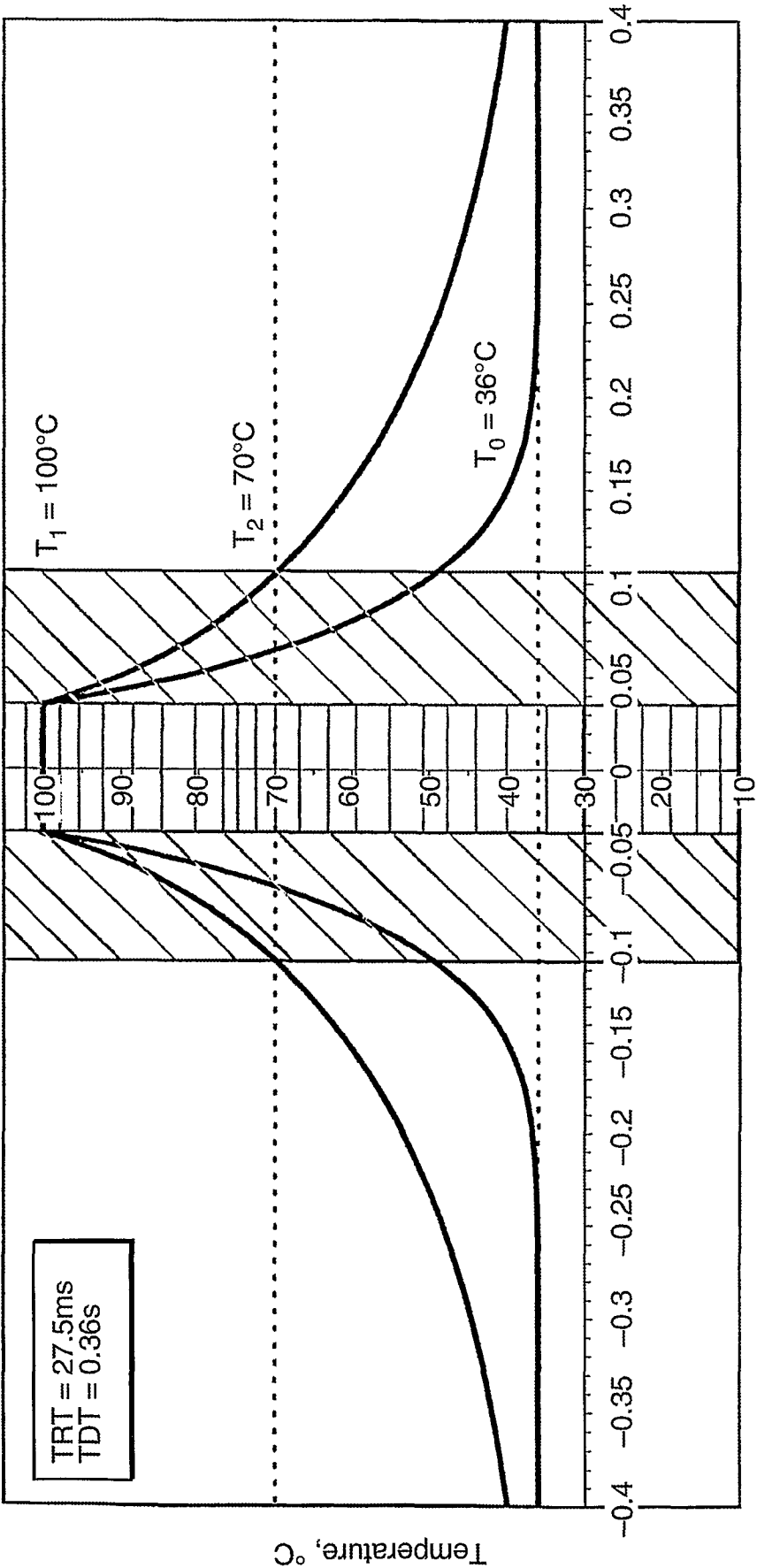
6/18



r, mm

FIG. 5a

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r, mm

FIG. 5b

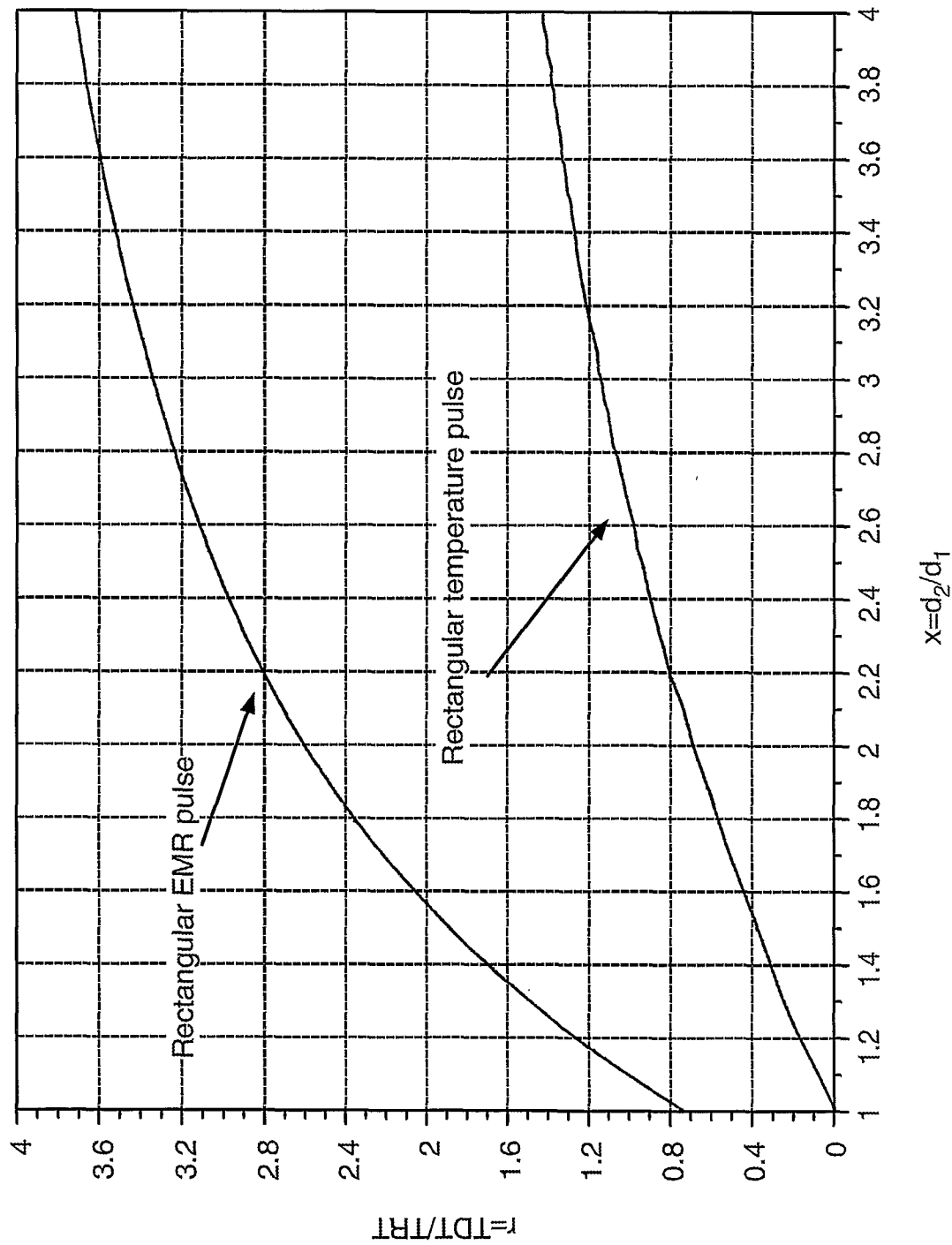


FIG. 6a

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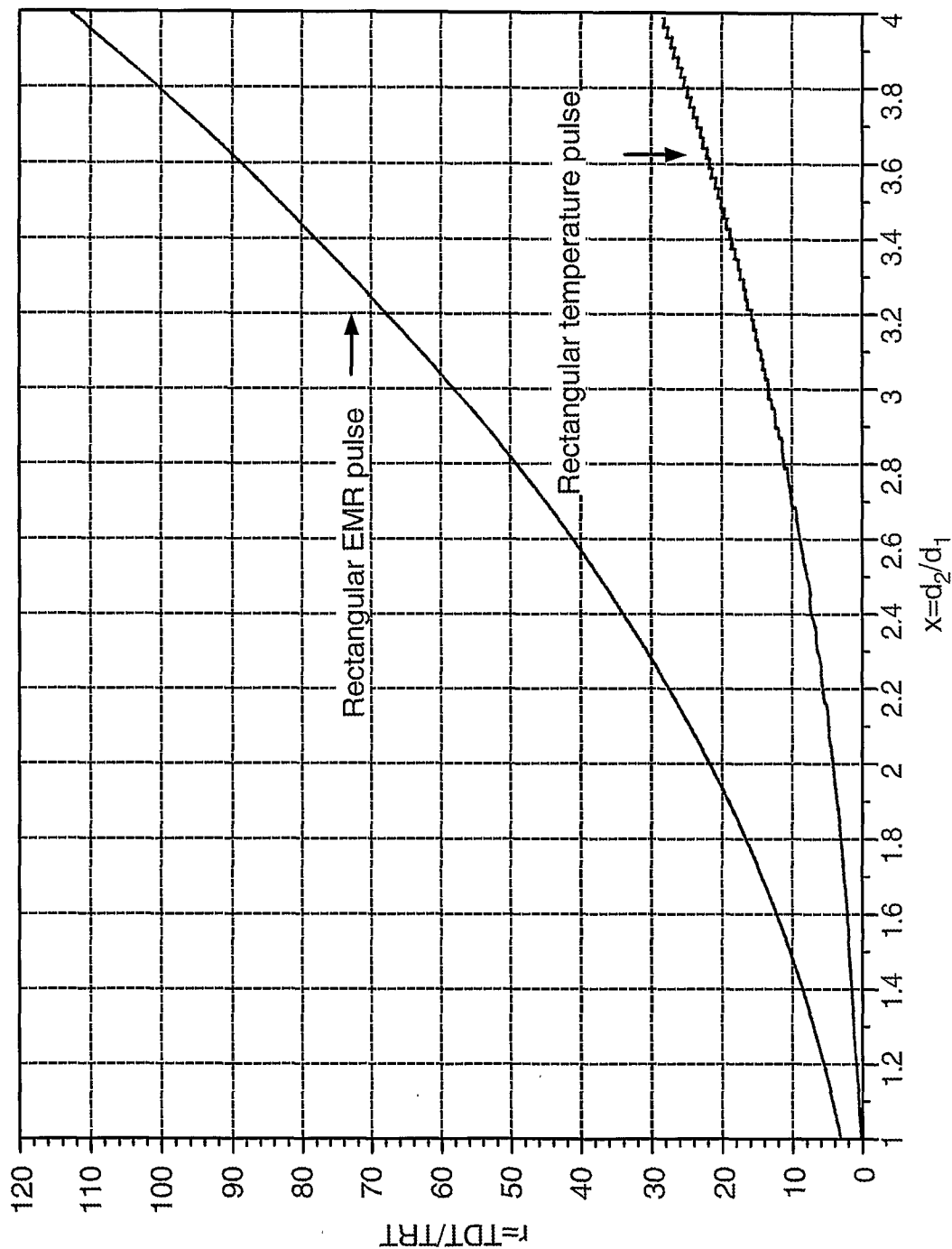


FIG. 6b

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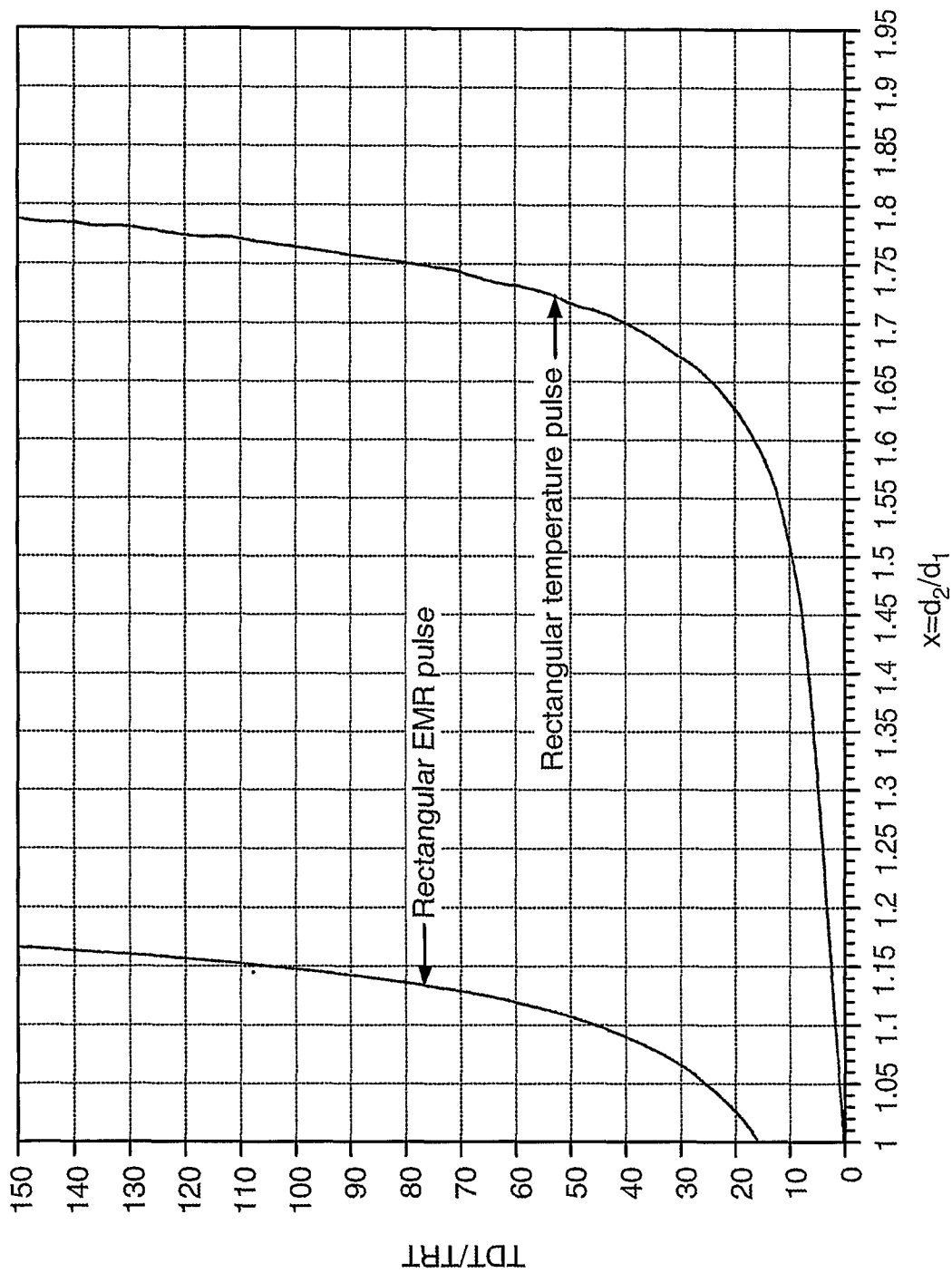


FIG. 6C

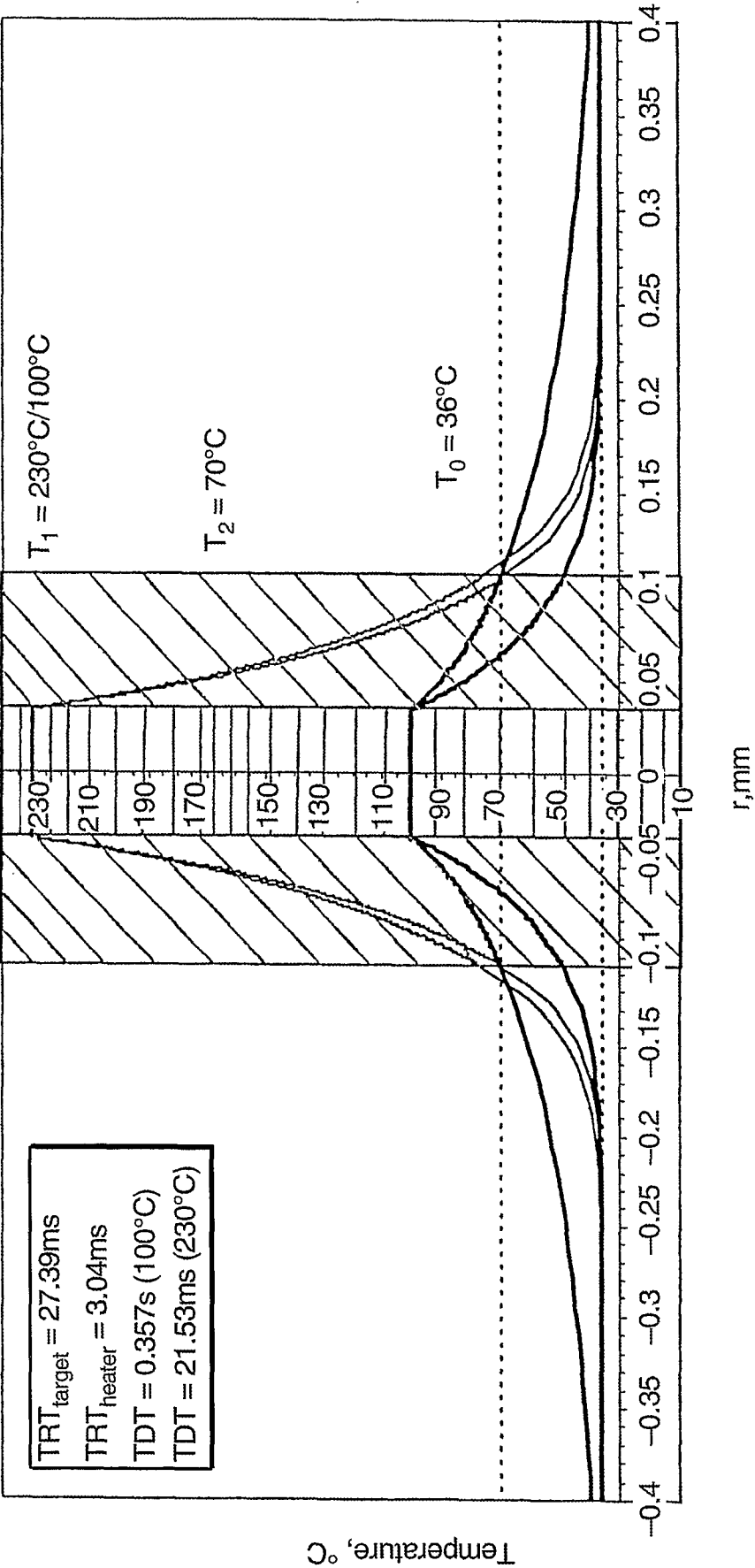


FIG. 7

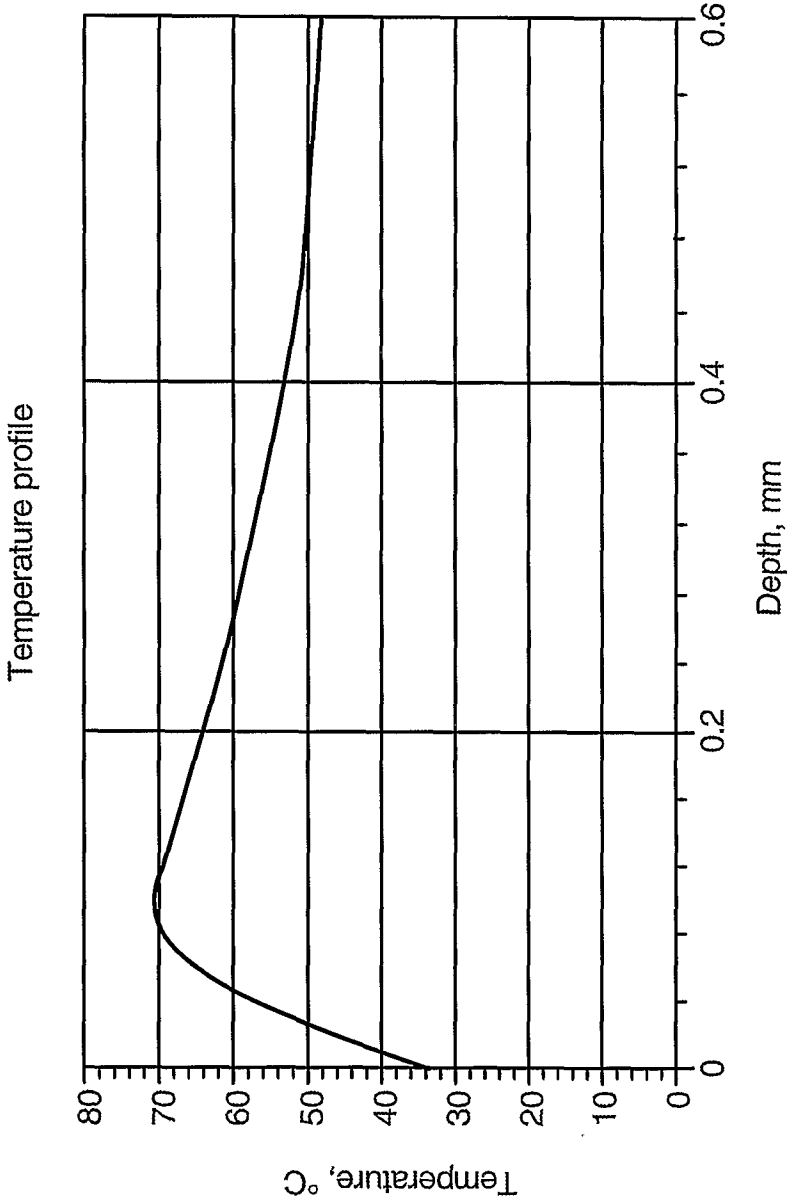


FIG. 8

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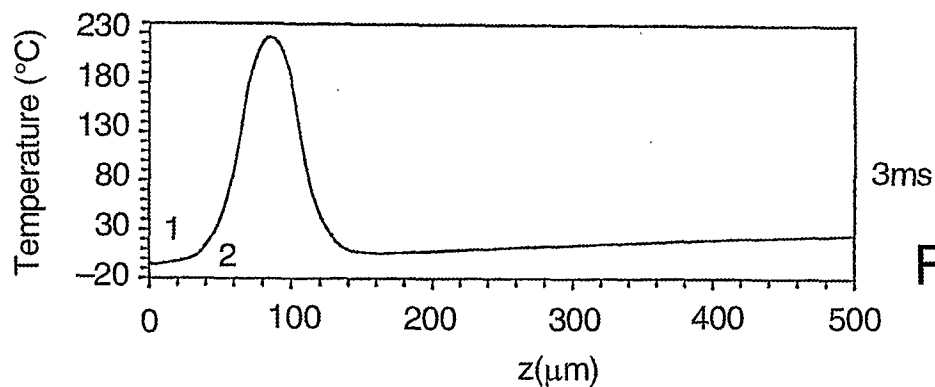


FIG. 9a

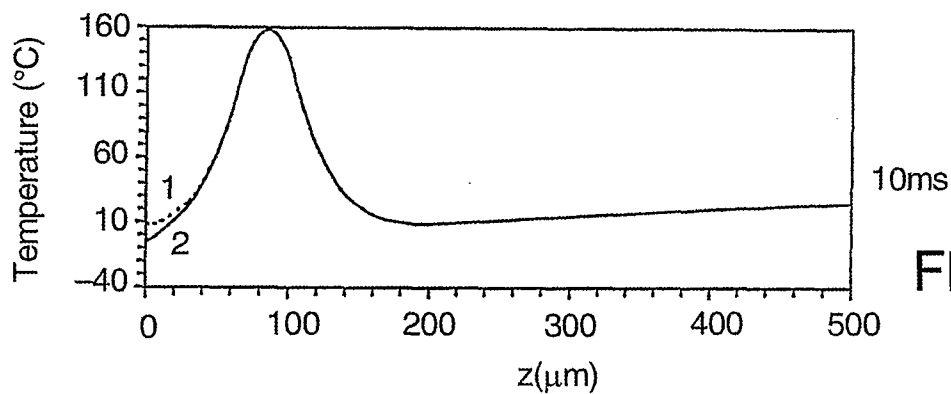


FIG. 9b

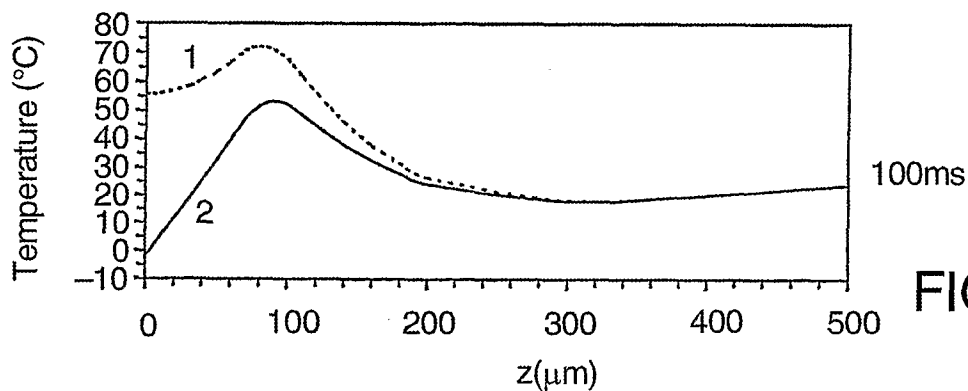


FIG. 9c

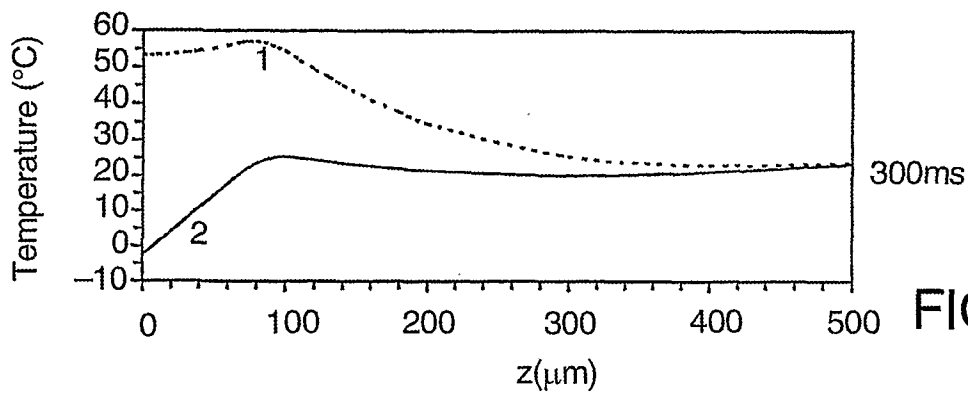


FIG. 9d

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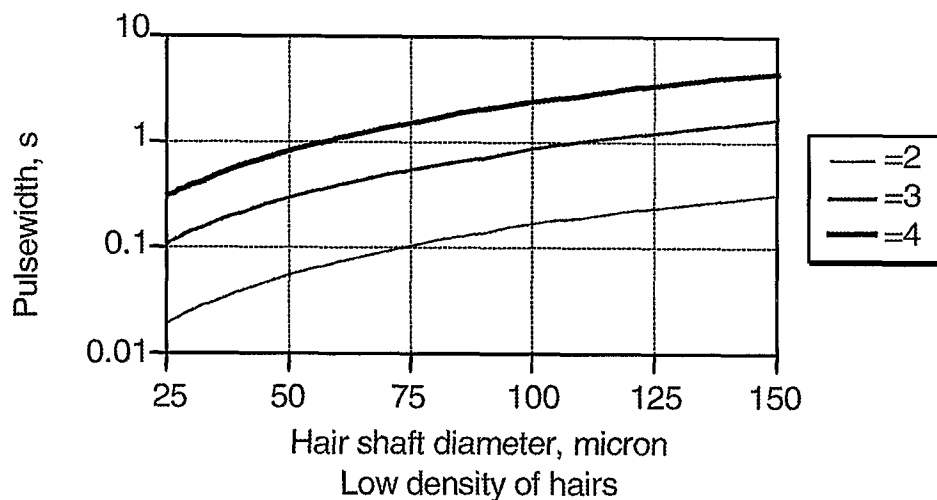


FIG. 10a

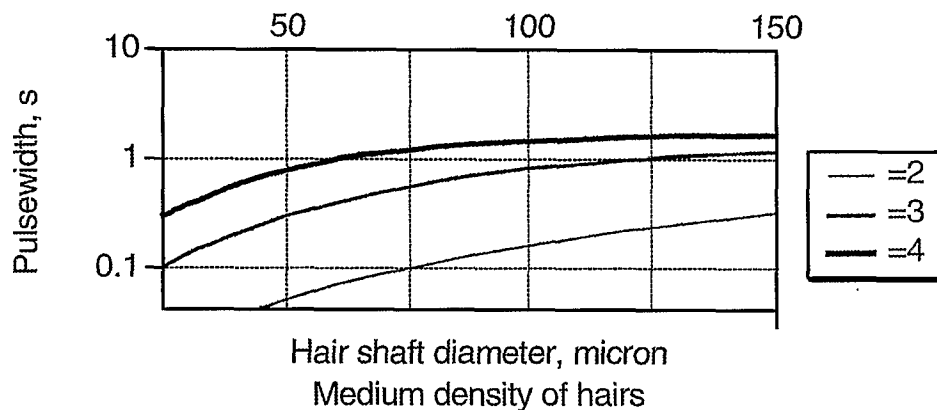


FIG. 10b

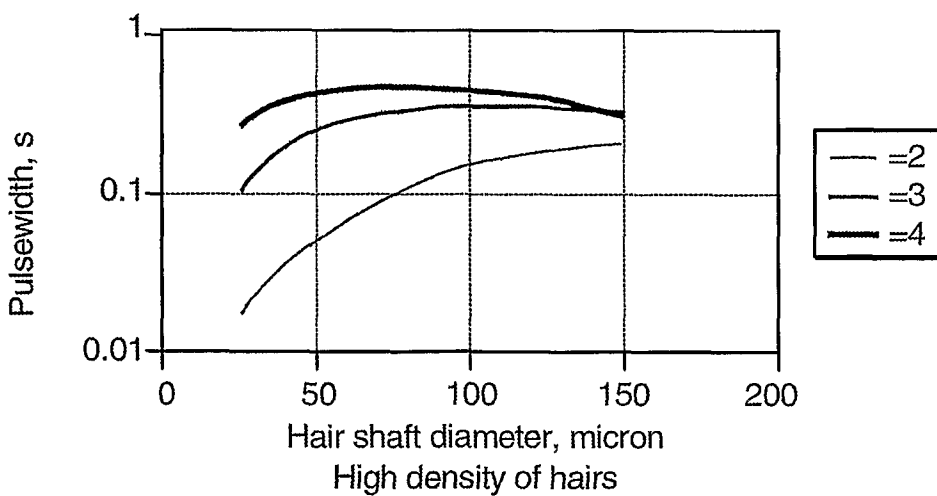


FIG. 10c

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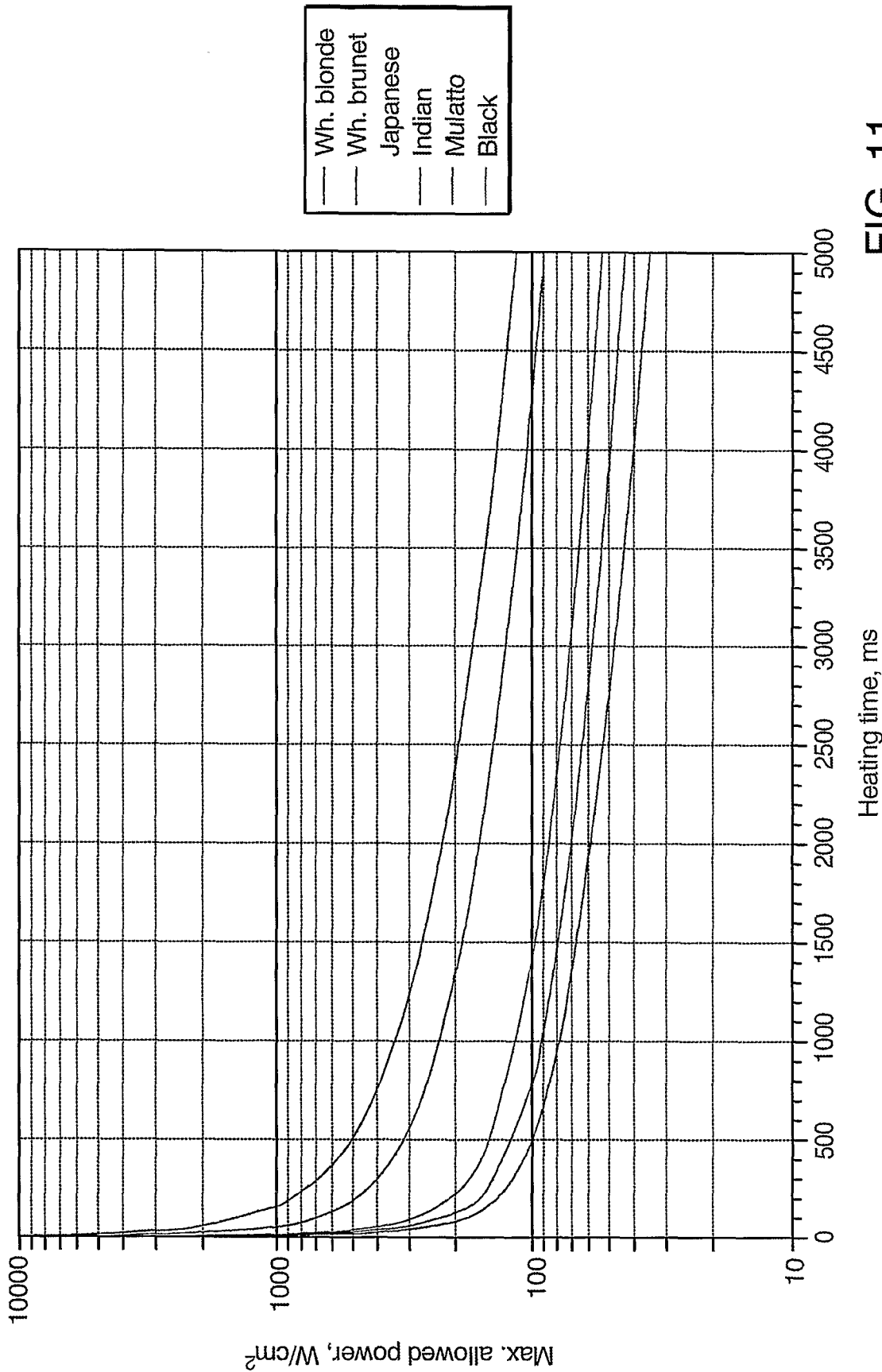


FIG. 11

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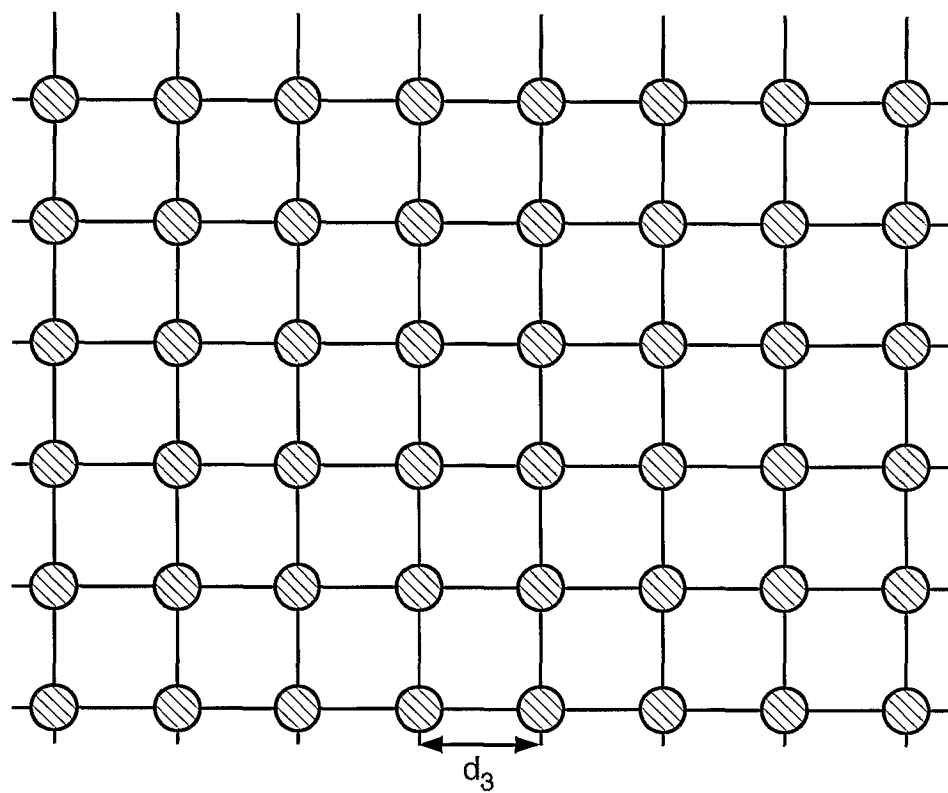


FIG. 12

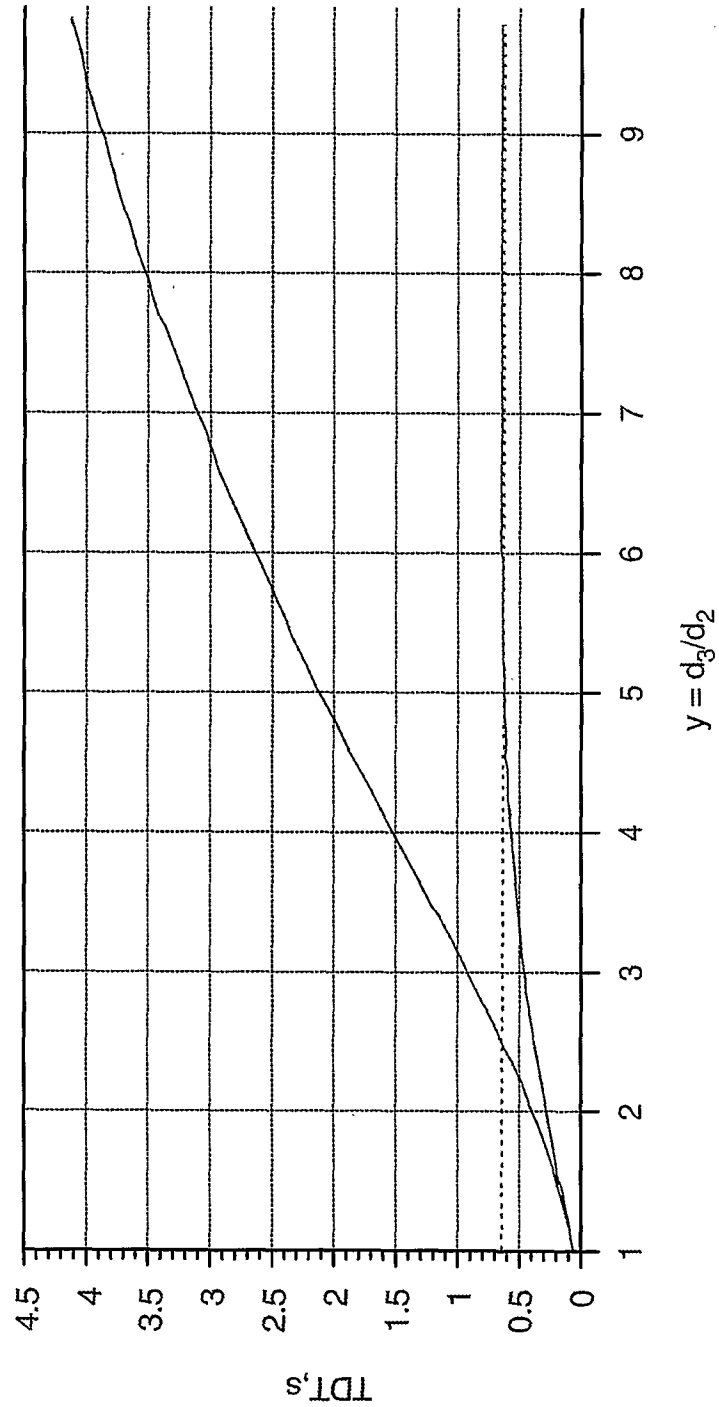


FIG. 13a

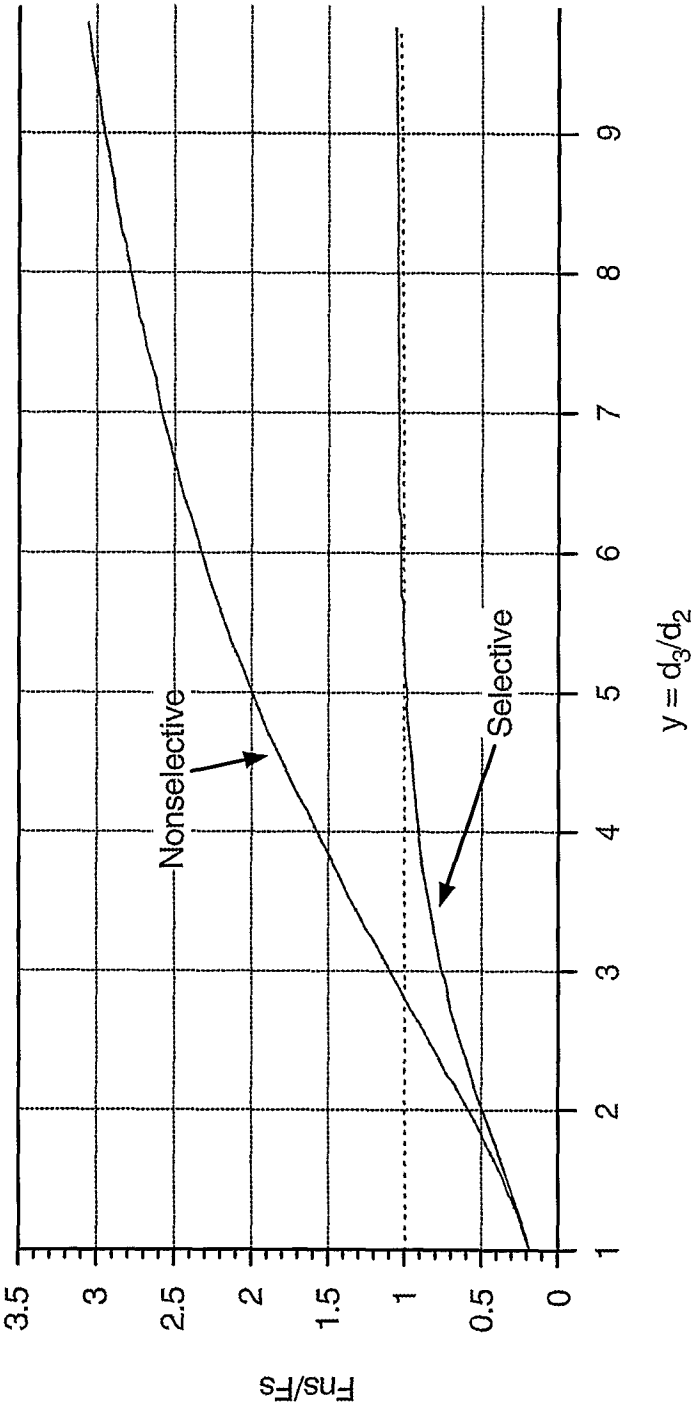


FIG. 13b

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 24507 A (THERMOLASE CORP) 11 June 1998 (1998-06-11) page 45, line 24 -page 46, line 14 page 50, line 8 -page 56, line 29 page 95, line 11 -page 101, line 20 ---	13-16, 18-26, 39-44, 57-60, 66-68
X	WO 99 29243 A (THERMOLASE CORP) 17 June 1999 (1999-06-17) page 24, line 25 -page 25, line 23 page 30, line 8 - line 22 page 36, line 5 - line 14 page 49, line 23 -page 51, line 30 --- -/--	13-16, 18-26, 39-44, 57-60, 66-68,71

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

16 May 2001

Date of mailing of the international search report

23/05/2001

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Petter, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/02511

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 51235 A (GEN HOSPITAL CORP ;PALOMAR MEDICAL TECHNOLOGIES I (US)) 19 November 1998 (1998-11-19) page 7, line 13 -page 9, line 30 page 16, line 6 - line 12 -----	13-27, 39-44, 57-60, 66-68
X	US 5 968 034 A (FULLMER DAVID J ET AL) 19 October 1999 (1999-10-19) column 9, line 49 -column 11, line 25 -----	13-27, 39-44, 57-60, 66-68,71

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/02511

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9824507	A	11-06-1998	AU 5375298 A	29-06-1998
			GB 2335147 A,B	15-09-1999
			US 6050990 A	18-04-2000
			US 6162211 A	19-12-2000
			ZA 9710967 A	29-03-1999
WO 9929243	A	17-06-1999	AU 3908099 A	28-06-1999
			GB 2335603 A	29-09-1999
WO 9851235	A	19-11-1998	AU 7568698 A	08-12-1998
			EP 0991372 A	12-04-2000
US 5968034	A	19-10-1999	US 5885274 A	23-03-1999
			EP 1018955 A	19-07-2000
			AU 8166798 A	04-01-1999
			WO 9858592 A	30-12-1998

(19) World Intellectual Property Organization
International Bureau



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WO 01/54770 A1

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(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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Published:

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR LOCALIZED LOW ENERGY PHOTON THERAPY (LEPT)

(57) Abstract: An apparatus for treating a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters. The apparatus has a power source, a central microprocessor with stored optical parameter protocols and wireless probes to receive the protocols and to generate and transmit the light. The invention also relates to a method for stimulating healing of a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters.



WO 01/54770 A1

**Title: METHOD AND APPARATUS FOR LOCALIZED LOW
ENERGY PHOTON THERAPY (LEPT)**

FIELD OF THE INVENTION

5 The invention relates to an apparatus for treating disorders of biological tissues with light of selected optical parameters. The invention also relates to methods for stimulating healing of disorders of biological tissue with light having selected optical parameters and to methods of stimulating healing of lesions using such light.

BACKGROUND OF THE INVENTION

10 Curing with light was known and used in medicine in ancient times. Red or ultraviolet light was successfully used in the 19th century for the treatment of pockmarks and lupus vulgaris by Danish physician, N.R. Finsen, the father of contemporary phototherapy.

15 Biological phenomena induced by ultraviolet light have been intensively investigated in photobiology and photomedicine for several decades. Ultraviolet light as a phototherapy for some dermatological diseases (mainly psoriasis) has been used since the early twenties. However, ultraviolet light is an ionizing radiation, and therefore has a damaging potential for biomolecules and has to be used in
20 photomedicine with certain precautions.

 Biological and healing phenomena induced by optical wavelength (visible) and infrared (invisible) light have been intensively investigated in the last decade. Electromagnetic waves with optical (visible light) and near infrared (invisible irradiation) wavelengths ($\lambda =$
25 400 - 2,000 nm) provide non-ionizing radiation and have been used *in vivo*, *in vitro* and in clinical studies, as such radiation does not induce mutagenic or carcinogenic effects.

 Lasers, specific light sources which provide narrow-band monochromatic, coherent, polarized light with wide range of powers and
30 intensities, have been widely used in medicine. Medical lasers may be subdivided into three groups according to their power and ability to

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5 produce heat: hot lasers, which are used in surgery; mid power lasers which are used in photodynamic therapy for cancer treatment or in dermatology to treat telangiectasia, port-wine stains, etc.; and low energy (or low intensity, cold or low level) lasers which deliver several orders of magnitude less energy to the tissue than surgical lasers. They produce very little heat in biological tissue or no heat at all.

10 Low energy lasers have been used in dermatology, traumatology and some other areas to enhance healing phenomena in the body (Mester et al., *Lasers Surg. Med.* 5:31-39, 1985; Trelles et al., *Lasers Surg. Med.* 7:36-45, 1987; Ohshiro T., *Laser Therapy: Practical Applications*, (Ed. T. Ohshiro), John Wiley, Chichester, 1991). The most frequently used terms for this area of physiotherapy are low Energy Laser Therapy (LELT), Low reactive Level Laser Therapy (LLLT), or Laser Therapy. The first successes of LELT were demonstrated in the treatment of chronic ulcers and persistent wounds of different etiology (Mester et al., *Lasers Surg. Med.* 5:31-39, 1985).

15 Anecdotal case studies have suggested that LELT is beneficial for a number of dermatological and musculoskeletal conditions. However, LELT has failed to provide good results in well-controlled randomized double-blind studies designed in accordance with rigorous North-American standards (Gogia and Marquez, *Ostomy/Wound Management*, 38:38-41, 1992; Lundeborg and Malm, *Ann. Plast. Surg.*, 27:53).

20 Coherence and polarization are the main features which differentiate laser light from regular monochromatic light. Many photoinduced phenomena in cell cultures and biotissue are reported to be induced by noncoherent, nonpolarized monochromatic light (Karu, *Health Physics*, 56:691-704, 1989 and Karu, *IEEE J. of Quantum Electronics*, QE23:1703-1717, 1987).

30 Laser beams lose coherence and polarization because of scattering very quickly after entering tissue and thus deeper tissue layers

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"do not distinguish" laser from non-laser light.

Low energy photon therapy (LEPT), also known as low energy, low level, low intensity laser therapy, photobiomodulation, is the area of photomedicine where the ability of monochromatic light to alter cellular function and enhance healing non-destructively is a basis for the treatment of dermatological, musculoskeletal, soft tissue and neurological conditions.

Low energy photons with wavelengths in the range of 400nm - 2,000 nm have energies much less than ultraviolet photons, and therefore, low energy photons do not have damaging potential for biomolecules as ionizing radiation photons have.

The area of LEPT research is controversial and has produced very variable results, especially in clinical studies. Almost every mammalian cell may be photosensitive, e.g. could respond to monochromatic light irradiation by changes in metabolism, reproduction rate or functional activity. Monochromatic light photons are thought to be absorbed by some biological molecules, primary photoacceptors, presumably enzymes, which change their biochemical activity. If enough molecules are affected by photons, this may trigger (accelerate) a complex cascade of chemical reactions to cause changes in cell metabolism. Light photons may just be a trigger for cellular metabolism regulation. This explains why low energies are adequate for these so called "photobiomodulation") phenomena. However, it is difficult to induce and observe these phenomena both *in vivo* and *in vitro* using the same optical parameters. Specific optical parameters are required to induce different photobiomodulation phenomena (Karu, *Health Physics*, 56:691-704, 1989; Karu, *IEEE J. of Quantum Electronics*, QE23:1703-1717, 1987). The range of optical parameters where "photobiomodulation" phenomena are observed may be quite narrow. The specificity and narrowness of the optical parameters required for "photobiostimulation" in LEPT therapy distinguishes LEPT therapy from the photodestruction

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phenomena induced by hot and mid power lasers (e.g. in surgery and PDT).

Devices for stimulating biological tissue using low energy light are disclosed for example in U.S. Patent No. 4,930,504 to Diamantopoulos et al. and U.S. Patent No. 4,686,986 to Fenyo et al., U.S Patent No 4,535,784 to Rohlicek describes an apparatus for stimulating acupuncture points using light radiation. U.S Patent No. 4,672,969 to Dew describes a method and apparatus for closing wounds using a laser tuned to a wavelength of 1.33 μm to produce thermal heating of the tissue to denature the protein.

To meet the changing requirements for optical parameters for different experimental and clinical applications, there is a need for an optical system for "photobiomodulation" having flexible parameters, adjustable for particular applications. In particular, there is a need for an apparatus capable of treating a range of biological disorders by reliably providing light to the affected three dimensional biological tissue, which light has the optical parameters necessary for inducing the appropriate photobiomodulation for the particular disorder and tissue to be treated. There is also a need for a method for reliably providing light having such parameters to a biological tissue having a disorder in order to effect healing.

SUMMARY OF THE INVENTION

The present inventors have determined that for each disorder of biological tissue there is a set of optical parameters which constitute the optimal protocol for treating the disorder by LEPT. The optimal protocol depends on a range of factors such as the type of tissue affected, the disorder, the stage of tissue healing (acute, subacute, tissue regeneration stage) and the size and three dimensional placement of the affected area. The optical parameters which make up the protocol include optical power, dose, intensity, wavelength, bandwidth, beam diameter and divergence, frequency and pulse duration. The present

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inventors have also determined that these protocols may be developed, stored, selected, retrieved from a microprocessor and utilized to provide optimal LEPT treatment for a range of biological disorders efficiently and reliably.

5 The present invention thus provides an apparatus for treating a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters. The apparatus comprises a power source for providing power to a central microprocessor; a central microprocessor having stored optical parameter protocols suitable for treating a range of disorders of biological tissue and
10 means for selecting one or more stored optical parameter protocols for the disorder to be treated; including at least one wireless optical probe, having a microprocessor in communication with the central microprocessor, to receive the selected optical parameter protocol and
15 having at least one probe containing an optical source(s) for generating a beam(s) of light having the selected optical parameter protocol and for directing the beam of light to the biological tissue to be treated; and communication means for transmitting the optical parameter protocol from the central microprocessor to the probes, or remotely via telephone
20 and satellite links to any location around the world or outer space.

 In an embodiment, the beam of light having the selected optical parameter protocol is substantially monochromatic and has a wavelength of from 400 to 2,000 nm and preferably has a wavelength in the range of from 500 to 2,000 nm, more preferably from 600 to 1,100 nm.
25 In particular, embodiments, preferred ranges include from 360 to 440 nm, from 630 to 700 nm, from 740-760 nm, or from 800-1,100 nm. The optical source may be, for example a laser, laser diode, superluminous or light emitting diode. In an embodiment, the optical source is in pulsed mode with an operating frequency in a range of from 0 to 200 Hz and 1,000 -
30 10,000 Hz for short pulses. In a further embodiment, the optical parameters are optical power, dose and intensity, frequency, modulation

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frequency and phase of stimulation.

The wireless communication means may be acoustic, magnetic or optical.

5 In a still further embodiment, the apparatus further comprises means for monitoring the condition of the mammal and providing feedback to the central microprocessor to adjust the selected optical parameter protocol based on the condition of the mammal. The means for monitoring the condition of the mammal may be for example EEG (electroencefalography), E MG (electromyography), E CG
10 (electrocardiography), CL (chemoluminescence) or a respirator, or a combination thereof.

In a further embodiment the apparatus comprised and utilized means to modulate treatment optical parameters by endogenous (such as respiratory, ECG, EEG, etc.) frequencies and to provide on-line feedback
15 for selection of stimulation phase in respect to any endogenous rhythm phases.

Another aspect of the invention relates to a method for stimulating healing of a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical
20 parameters provided by a central microprocessor having stored optical parameter protocols suitable for treating a range of disorders of biological tissue; selecting one or more stored optical parameter protocols for the disorder to be treated; generating a beam of light having the selected optical parameter protocol and directing the beam of light to the
25 biological tissue to be treated.

In an embodiment, the invention provides a method of stimulating healing of a lesion in a mammal, comprising: irradiating the lesion with a substantially monochromatic beam of light having predetermined optical parameters, wherein the predetermined optical
30 parameters include a dose of from 0.2 to 10 J/cm², an intensity of from 0.2 to 5,000mW/cm² and a wavelength of from 400 to 2,000 nm.

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In a particular embodiment of the method, the lesion is a chronic ulcer or wound and the selected optical parameters include a dose of from 0.2 to 1.0 J/cm², an intensity of from 0.2 to 10mW/cm² and a wavelength of from 600 to 700 nm. In another embodiment of the method, the lesion is an acute ulcer or wound and the selected optical parameters include a dose of from 2.0 to 5.0 J/cm², an intensity of from 10.0 to 30 mW/cm² and a wavelength of from 600 to 700 nm. In yet another embodiment, the lesion is an infected wound and the selected optical parameters include a dose of from 3.0 to 7.0 J/cm², an intensity of from 50.0 to 80 mW/cm² and a wavelength of from 600 to 700 nm.

Other objects, features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

DESCRIPTION OF THE DRAWINGS

The invention will be better understood with reference to the drawings in which:

Figure 1 is a schematic flow chart illustrating the development of LEPT optical parameter protocols;

Figure 2 is a graph showing the percentage of the dose on the skin surface $(D(z)/(1-R)D_0) \times 100\%$ received by cells at skin depth \bar{z} and at wavelengths $\lambda=630$ nm (wavelength 1) and $\lambda=1,060$ nm (wavelength 2), (for explanation of parameters D_0 , D and R see the following detailed description);

Figure 3 is a graph showing the results of Monte-Carlo simulation of photon propagation in the skin;

Figure 4 is a schematic view showing major optical pathways in

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human skin;

Figure 5 shows a simplified two-dimensional diagram of desired parameters for low energy photon therapy for a particular condition and an example of the range produced by a typical given laser;

5 Figure 6 is a plan view showing how Figure 6-1, Figure 6-2, Figure 6-3 and Figure 6-4 are assembled to form a complete circuit diagram of a base unit according to the invention;

Figure 6-1 is the first part of the circuit diagram referred to in Figure 6;

10 Figure 6-2 is the second part of the circuit diagram referred to in Figure 6;

Figure 6-3 is the third part of the circuit diagram referred to in Figure 6;

15 Figure 6-4 is the fourth part of the circuit diagram referred to in Figure 6;

Figure 7 is a plan view showing how Figure 7-1, Figure 7-2 and Figure 7-3 are assembled to form a complete circuit diagram of a probe unit according to the invention;

20 Figure 7-1 is the first part of the circuit diagram referred to in Figure 7;

Figure 7-2 is the second part of the circuit diagram referred to in Figure 7;

Figure 7-3 is the third part of the circuit diagram referred to in Figure 7;

25 Figure 8 is a diagrammatic view of a remote probe unit according to the invention;

Figure 9 is a perspective view of a probe unit according to the invention;

30 Figure 10 is a perspective view of the probe unit of Fig. 9 from the opposite side;

Figure 11 is a diagrammatic view showing various patterns of

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diodes for use with the invention;

Figure 12 is a schematic view showing alternative patterns of diodes according to the invention;

Figure 13 is a perspective view of a flexible probe unit according to the invention; and

Figure 14 is a perspective view of a ring probe according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

As hereinbefore mentioned, the present invention provides an apparatus for treating a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters. The apparatus comprises a power source for providing power to a central microprocessor; a central microprocessor having stored optical parameter protocols suitable for treating a range of disorders of biological tissue and means for selecting one or more stored optical parameter protocols for the disorder to be treated; at least one wireless probe, having a microprocessor in communication with the central microprocessor, to receive the selected optical parameter protocol and having at least one probe containing an optical source for generating a beam of light having the selected optical parameter protocol and for directing the beam of light to the biological tissue to be treated; and wireless communication means for transmitting the optical parameter protocol from the central microprocessor to the wireless heads.

A wide range of disorders of biological tissue or their symptoms may be treated by the apparatus of the invention, including acute and chronic musculoskeletal conditions, such as arthritis, degenerative disc and joint diseases, bone spurs, back and joint pain, tendinitis, muscle pain and stiffness, myofascial pain; post surgical complications, such as swelling, inflammation, scarring and stiffness; acute trauma and chronic post-traumatic conditions in the soft tissues and bones, including sprains,

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strains, wounds, whiplash; repetitive strain injuries such as carpal tunnel syndrome, tennis and golfer's elbow; neurological and neuromuscular conditions; dermatological conditions such as burns, acne, herpes simplex, and ulcers, including infected or non-infected
5 chronic ulcers of different etiology such as venous ulcers, diabetic ulcers, decubitus ulcers, pressure sores, burns and post-traumatic ulcers.

There are many optical parameters, including the type of the light source, optical power, intensity, dose, frequency and pulse duration, wavelength and bandwidth, beam diameter and divergence, three-
10 dimensional light distribution etc. which may be selected to provide an optimized protocol to treat the disorder. The individual optical parameters may be selected based on the disorder to be treated, as described below. The development of appropriate treatment protocols was carried out as indicated by the flow chart of Fig. 1.

15 **Optical Power**

Optical power may be provided in continuous wave mode or pulse mode. In continuous wave mode for a single optical source, optical power P is a total energy of emitted light per second and measured in Watts (W) or Milliwatts (mW). The total power P_t in a cluster probe is

20
$$P_t = n \times P \quad (1)$$

P is the power of a single optical source, and n is the number of optical sources per probe.

The power of a single optical source or cluster probe has to correspond to the type of tissue disorder to be treated. For example, for
25 the treatment of so-called acupuncture points or spinal nerve roots, less power in a single probe is required compared to the treatment of trigger points. The total power in a cluster should be physiologically justified and can vary from application to application. For example, neck and face areas are more sensitive, in general, to LEPT compared to the rest of the

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body and, therefore, their treatment requires less power in the cluster probe. There is some maximum total power in a cluster probe for every particular wavelength up to which patients can respond to LEPT with comfort. Exceeding certain limits in the total power of a cluster probe could lead to overdose, excessive stress for the patient and sometimes to exacerbation of the patient's condition.

Optical sources in a pulsed mode are described by peak power P_p , average power P_{av} , pulse frequency $F(\text{Hz})$ and pulse duration $\tau(\text{s})$. Average power P_{av} is less than peak power P_p and can be controlled by changing the frequency in accordance with the following formula

$$P_{av} = P_p \times F \times \tau \quad (2)$$

Power by itself is not a decisive factor for LEPT, the power density (intensity mW/cm^2) is more important for "photobiomodulation" phenomena. Physiologic tissue response first of all depends on light intensity and dose. Intensity (mW/cm^2), and dose (J/cm^2) are optical parameters which skin or biotissue can "feel".

Table 1 below shows suitable power ranges for different tissue pathologies.

Table 1

Tissue pathology, area (points) to be treated	Wavelength range, (nm)	Single optical probe. Range of powers (mW)	Cluster probe. Range of powers (mW)
Spinal nerve roots	800-1,100	1-70	---
Tender trigger points	a) 630-700 b) 800-1,000	5-50 5-150	---

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Tissue pathology, area (points) to be treated	Wavelength range, (nm)	Single optical probe. Range of powers (mW)	Cluster probe. Range of powers (mW)
Ulcer, wound	a) 630-700	5-30	30-150
	b) 800-1,100	10-50	30-200
Acute post-traumatic inflammation in soft tissue (all body, except face)	a) 630-700	---	30-150
	b) 800-1,100	---	50-200
Chronic inflammation (flare-up stage) in soft tissue (all body except face)	800-1,100	---	20-100
Chronic inflammation (no flare-up) in soft tissue (all body except face)	800-1,100	---	50-200
All types of inflammation in face soft tissues	a) 630-700	---	20-50
	b) 800-960	---	30-100

Intensity (power density)

Intensity is the rate of light energy delivery to 1 cm² of skin or biotissue. Intensity is measured in milliwatts per cm² (mW/cm²). Real intensity on the skin surface depends on light reflection and scattering from the skin and underlying tissue layers. The light intensity on the skin surface can be calculated with the following formula

$$I = (I - R) \times 4 \times P / \pi d^2 \quad (3)$$

where P (or Pav for pulsed mode) is the optical power, d(cm) is the beam diameter and R is the reflection coefficient. Coefficient R can vary from

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0.4 up to 0.75 for different wavelengths and depends also on the skin type and condition. For applications using non-contact techniques a portion of the optical power (and dose) equal to $R \times P$ is lost because of the reflection. Back scattering has to be taken into account for LEPT dosimetry as well. For contact technique applications, less power is lost due to the repeating light reflection back to the skin surface from optical source parts. Therefore, for the same optical source LEPT dosimetry would be different depending on the type of technique used (contact or noncontact). Particular "photobiomodulation" phenomenon can best be activated within narrow ranges of parameters (e.g. see Tables 2, 5, which appear later in this description). For example, collagen type I production is thought to be affected by LEL in an inverse manner to fibroblast proliferation: when cell proliferation is increased, collagen type I production is decreased and vice versa (van Breugel and Bar, 1992, *Laser Surg. Med.* 12:528-537). In cell culture experiments thin cell layers are usually uniformly exposed to light therefore intensity does not change significantly within the sample. For biotissue stimulation, the whole picture is different because light intensity (and dose) decreases with depth z . In the skin and subcutaneous tissue layers light intensity can be approximately described by the following formula (Beer's law):

$$I(z) = I_0 (1 - R) \exp(-\alpha z)$$

$$I(z) = \frac{(1 - R) \times 4 \times P \times \exp(-\alpha z)}{\pi d^2} \quad (4)$$

where $I(z)$ (W/cm^2 or mW/cm^2) - is the fluence rate (intensity or power density) at the depth z (mm); $I_0 = P/S$ - incident intensity; P - beam power; $S = \pi d^2/4$ is a beam area for a cylindrical parallel beam of diameter d (cm); and α (mm^{-1}) is the attenuation coefficient which depends on light absorption and scattering. This formula may be used to calculate

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intensity and dose for every particular tissue layer.

Suitable intensities for biostimulation are in the range of from 0.1 to 5,000 mW/cm². For stimulating healing of chronic ulcers or wounds intensity may preferably be in the range of from 0.2 to 10 mW/cm², for ulcers or wounds in acute inflammatory stage a preferred range is from 10.0 to 30 mW/cm² and for infected wounds a preferred range is from 50 to 80 mW/cm². Table 2 below shows suitable ranges of intensities for different tissue pathologies.

Table 2

Ranges of Intensities for Different Tissue Pathologies

Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Intensity range mW/cm ²
1	1 Ulcers or wounds, stimulation of repair processes	2 630-700	3 0.2-10
2	Ulcers, wounds, acute inflammatory condition	630-700	10-30
3	Infected wounds	630-700	50-80
4	Area of ulcers or wounds with impaired microcirculation, or to treat such areas and also the area surrounding the ulcer, wound	800-1,100	300-600
5	Post-surgical scar, acute inflammatory condition	630-700	10-30
6	Post-surgical scar, sub-acute inflammatory condition	800-1,100	10-40 60-100 300-600 1,000-5,000
7	Herpes simplex and acne	630-700	20-60

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Intensity range mW/cm ²
8	Acute post-traumatic inflammation in soft tissue	a) 630-700 b) 800-1,100	10-40 30-100
9	Post-traumatic condition in soft tissue accompanied by hematoma, bruise	630-700	20-50
10	Post-traumatic condition, sub-acute stage	800-1,100	a) 10-40 b) 60-100 c) 300-600 d) 1,000-5,000
11	Post-traumatic condition, regeneration of tissue, normalization of function	800-1,100	a) 60-100 b) 300-600 c) 1,000-5,000
12	Chronic inflammation in soft tissue (flare-up stage), treatment of the affected area	a) 630-700 b) 880-1,100	1-5 1-10
13	Chronic inflammation in soft tissue (flare-up stage), treatment at selected points* or areas** on the body	630-700 800-1,100	1-10 10-30 100-300
14	Chronic inflammation in soft tissue (no flare-up)	a) 630-700 b) 800-1,100	5-30 10-40 60-100 300-600 1,000-5,000
15	Degenerative joint diseases (arthritis, rheumatoid arthritis, degenerative disk disease, etc.), treatment of the affected area	630-700 800-1,100	1-10 10-30 60-100 300-600 1,000-5,000

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Intensity range mW/cm ²
16	Degenerative joint diseases (arthritis, rheumatoid arthritis, degenerative disk disease, etc.), treatment of selected points* or area(s)** on the body	630-700 800-1,100	1-10 100-300
17	Muscle spasm relief	a) 630-700 b) 800-1,000	1-10 1-40 60-100 300-600 1,000-10,000
18	Localized pain relief	800-1,100	60-100 300-600 1,000-10,000
19	Tender, trigger point therapy	800-1,100	300-600 1,000-10,000
20	So called acupuncture point therapy	a) 630-700 b) 800-1,100	1-10 60-100 300-600 3-15 60-100 300-600
21	Carpal tunnel syndrome	800-1,100	1-10 60-100 300-600 1,000-10,000
22	Neuritis, neuralgia, trigeminal neuralgia	800-1,100	1-10 20-40 100-400 800-3,000

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Intensity range mW/cm ²
23	Post-traumatic, post-surgical complications, arthritis accompanied by swelling, edema, pain	630-700 800-1,100	10-40 300-600 1,000-5,000

* Selected points on the body may include tender and trigger points, related acupuncture points, spinal nerve roots, points along related nerves' pathways.

** Selected area(s) on the body may include related dermatomes, spine areas, nerves' pathways.

Beam Diameter and Divergence

Beam diameter and divergence are important features of single optical sources. Beam size affects light intensity values on the skin surface and within the tissue in accordance with formulae (3, 4). Beam divergence affects light distribution and dosimetry for different tissue layers. For non-contact techniques light spot size and irradiated area S on the skin surface depend on the distance to the irradiated surface h as follows:

$$S = \frac{\pi}{4} \times (d + 2h \times \tan \alpha)^2 \quad (5)$$

where d is the beam diameter near the probe tip, 2α is the diverging angle, $2h \times \tan \alpha$ is the additional beam diameter due to beam divergence.

Different optical sources (lasers, laser diodes, light emitting diodes, etc.) have different beam divergences. Lasers usually have small

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beam divergency, laser diodes and LED's have bigger divergences. For different applications particular beam divergences are more convenient. For example, for the treatment of wounds and ulcers, almost parallel beams are less desirable because of the large areas to be treated, and
5 optical sources with some particular divergence are more convenient.

The beam diameter and divergence should be selected based on the three dimensional size and shape of the tissue area affected. Preferably, the beam diameter and divergence should be selected such that the area receiving LEPT is just slightly larger in size than the area
10 affected. The appropriate radius of the beam may be calculated by the following formula :

$$(R+ 1)^2/R^2$$

where R (cm) equals the radius of the area affected by the disorder. In the case of lesions, such as ulcers or other open skin wounds, it is particularly
15 important that too large an area not be illuminated as, where the illuminated area is much larger than the lesion, the skin ulcer (wound) healing rate is not optimized. As the ulcer is treated and healed the area requiring treatment and the beam diameter will have to be reduced.

Dose

20 The dose D is the light energy provided to the unit of surface (1cm²) during a single irradiation and measured in J/cm² or mJ/cm². The light dose received by the skin surface is

$$D=I \times t \quad (6)$$

where I is the intensity on the skin surface, and t is the exposure time (s).
25 The dose received by subcutaneous tissue layer at the depth z for a parallel beam can be calculated by the following formula:

$$D=I(z) \times t \quad (7)$$

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where $I(z)$ is given by formula (4).

As mentioned above, the dose alone does not ensure particular photoeffect or healing phenomenon. Only proper selection of the whole set of optical parameters including dose will provide the desirable therapeutic effect. The selection of optical parameters depends on the medical condition, location of the affected areas, person's age, etc. Particular examples will be provided below.

The percentage of dose $(D(z)/(1-R)D_o) \times 100\%$ on the skin surface received by cells at a skin depth \bar{z} at wavelengths of 630 nm and 1,060 nm is shown in Table 3 and is illustrated in Fig. 2. All curves $D(z)$ for different wavelengths in the interval (630-1,060) nm depend on corresponding reflectance R_λ and attenuation α_λ coefficients (see Table 4) and are located between curves 1 and 2 on Fig. 2.

1. $D(J/cm^2)$ is the actual dose (fluence) received by cells at depth \bar{z} .

2. $R = R_s + R_T$ - diffuse reflectance

R_s - regular reflectance from the skin surface

R_T - is the remittance from within the tissue

3. $D_o = I_o \times t$ - conventionally calculated dose

t = exposure time

4. $I_o = P/S$ - incident intensity

(P - beam power; S - beam area)

The actual doses received by different cell types in the skin exposed to LEPT are illustrated in Table 3. The maximum dose ($D \sim (0.5-1.3) D_o$) is received by keratinocytes and Langerhans cells from the epidermis. Cells from dermis (fibroblasts, mast cells, blood and nerve cells) are exposed to significantly less dose than the incident one $D \sim (0.05-$

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0.3) D_o . The least dose $D \sim 0.3 D_o/t$ is received by blood cells moving through capillaries (velocity ~ 1 mm/sec).

Table 3

**Actual dose received by different cells in
the skin exposed to LEP radiation**

5

Cell type	Formulae for actual dose calculation	Typical range of doses
Keratinocytes Langerhans cells	$(0.5-1.8) D_o (1-R)$	$(0.5-1.3) D_o$
Fibroblasts mast cells nerve cells not moving blood cells	$(0.05-0.5) D_o (1-R)$	$(0.05-0.3) D_o$
moving blood cells	$(0.05-0.5) D_o (1-R) \times (2/t)$	$0.3 D_o/t$

where D_o (J/cm²) is a conventionally calculated dose

Table 4

**Diffuse reflectance R_λ , attenuation coefficients α_λ
and penetration depths d_λ for some wavelengths**

λ (nm)	R_λ	$I - R_\lambda$	α_λ (mm ⁻¹)	d_λ (mm)
630	0.6	0.4	1.6	0.6

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820	0.5	0.5	1.0	1
900	0.45	0.55	0.8	1.25
1,060	0.5	0.5	0.6	1.7

d(mm) - penetration depth

$$\alpha_{\lambda} d_{\lambda} = I \quad I(d) = 0.37I_0$$

5 Suitable doses for photobiomodulation are in the range of from 0.1 to 20 J/cm², preferably from 0.2 to 5 J/cm². For stimulating healing of chronic ulcers or wounds doses may preferably be in the range of from 0.05 to 0.2 J/cm², for ulcers or wounds in acute inflammatory stage a preferred range is from 2 to 5 J/cm² and for infected wounds a preferred range is from 3.0 to 7.0 J/cm². See Table 5 below for ranges and doses (in Joules/cm²) for different tissue pathologies.

10

Table 5Ranges of doses for different tissue pathologies

Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Dose range, J/cm ²
1	1 Chronic ulcers or wounds, stimulation of healing	2 630-700	3 0.05 - 0.2
2	Ulcers, wounds, acute inflammatory condition	630-700	2-5
3	Infected wounds	630-700	3-9
4	Area of ulcers or wounds with impaired microcirculation, or to treat such area and also the area surrounding the ulcer, wound	800-1,100	0.1-9

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Dose range, J/cm ²
5	Post-surgical scar, acute inflammatory condition	630-700	2-5
6	Post-surgical scar, sub-acute inflammatory condition	800-1,100	3-7 4-25
7	Herpes simplex and acne	630-700	4-9
8	Acute post-traumatic inflammation in soft tissue	a) 630-700 b) 800-1,100	3-9 3-10
9	Post-traumatic condition in soft tissue accompanied by hematoma, bruise	630-700	5-14
10	Post-traumatic condition, subacute stage	800-1,100	3-7 4-25
11	Post-traumatic condition, regeneration of tissue, normalization of function	800-1,100	3-5 4-25
12	Chronic inflammation in soft tissue (flare-up stage), treatment of the affected area	a) 630-700 b) 880-1,100	0.1-0.5 0.1-0.5
13	Chronic inflammation in soft tissue (flare-up stage), treatment of selected points* or area(s)** on the body	630-700 800-1,100	0.1-0.6 1-5
14	Chronic inflammation in soft tissue (no flare-up)	a) 630-700 b) 800-1,100	2-7 2-9 3-25 25-100

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Dose range, J/cm ²
15	Degenerative joint diseases (arthritis, rheumatoid arthritis, degenerative disk disease, etc.), treatment of the affected area	630-700 800-1,100	0.1-0.5 2-9 3-25 25-100
16	Degenerative joint diseases (arthritis, rheumatoid arthritis, degenerative disk disease, etc.), treatment of selected points* or area(s)** on the body	630-700 800-1,100	0.1-0.5 1-5
17	Muscle spasm relief	a) 630-700 b) 800-1,100	0.1-0.3 0.1-0.5 3-5 4-25 25-100
18	Localized pain relief	800-1,100	8-150
19	Tender, trigger point therapy	800-1,100	4-150
20	So-called acupuncture point therapy	a) 630-700 b) 800-1,100	0.02-0.2 0.1-1.0 2-4 0.06-0.4 0.1-2.0 2-4
21	Carpal tunnel syndrome	800-1,100	0.05-0.3 0.2-4.0 5-10 25-150

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Protocol #	Tissue pathology, area (point) to be treated	Wavelength range, nm	Dose range, J/cm ²
22	Neuritis, neuralgia, trigeminal neuralgia	800-1,100	0.1-0.3 1-3 5-25 25-80
23	Post-traumatic, post-surgical complications, arthritis, accompanied by swelling, edema, pain	630-700 800-1,100	5-14 25-100

* Selected points on the body may include tender and trigger points, related acupuncture points, spinal nerve roots, points along related nerves' pathways.

** Selected area(s) on the body may include related dermatomes, spine areas, nerves' pathways.

Frequency and Pulse Duration

Low range frequencies of 0-200Hz may sensitize release of key neurotransmitters and/or neurohormones (e.g. endorphins, cortisol, serotonin). These frequencies correspond to some basic electromagnetic oscillation frequencies in the peripheral and central nervous system (brain). Once released these neurotransmitters and/or neurohormones can modulate inflammation, pain or other body responses. Analogous phenomena can be expected with "photobiomodulation" within the same range of low frequencies. Certainly, the interaction between living cell and pulsed electromagnetic wave depends on wavelength as well as pulse duration. Pulse repetition rates within the range 1,000-10,000Hz with different pulse durations (milli-, micro- or nanoseconds) can be

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used to change average power. Specific pulse repetition rates to induce particular healing mechanism are reflected in Table 6 below.

Table 6

Ranges of frequencies for stimulation of particular healing mechanisms

Healing mechanisms stimulated	Basic frequency (Hz) or continuous wave mode	Endogenous modulation frequency (Hz)
Endorphin release	1-5	---
Capillar microcirculation improvement	9-11 50-200	1-1.2 (average frequency of heart beating) 0.2-0.3 (average frequency of breathing cycle)
Localized muscle spasm and pain relief	50-120 or Continuous wave mode	1-5 0.2-0.3
Lymph flow enhancement	continuous wave mode	1-1.2 0.2-0.3
Stimulation of tissue repair	continuous wave mode or 100 Hz	1.2 0.2-0.3

5 Three Dimensional Light Distribution

Depending on the target tissue for LEPT (e.g. skin, muscle, ligament) a proper three-dimensional light distribution should be provided to get the desirable physiologic and therapeutic response. For single optical sources important parameters affecting light distribution are beam size, divergence, light wavelength as well as biotissue optical properties (reflection, absorption, scattering, refraction). Total reflectance is equal to the sum of the regular reflectance from the skin surface and the remittance from within the tissue (see Fig. 4).

10

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For cluster probes, additional contributive parameters are the distance between diodes and the cluster probe's three-dimensional shape. All these parameters should be physiologically justified to provide optimal biotissue response and requirable three-dimensional light distribution. For example, the distance between diodes can affect vasoactive blood vessel response and average energy density delivered to the treated area. For proper vasoactive response a definite distance between diodes has to be provided depending on particular parameters of a singular diode (power, beam, diameter, divergence).

The three-dimensional light distribution in tissues such as the skin and underlying tissue layers may be calculated based on diffusion approximation and/or the Monte Carlo approach (L. Wang and S. Jacques, Hybrid model of Monte Carlo Simulation and diffusion theory for light reflectance by turbid media, J. Opt. Soc. Am. A/Vol. 10, No. 8, 1993, pp 1746-1752; A. Welch et al., Practical Models for Light Distribution in Laser-Irradiated Tissue, Lasers in Surg. Med. 6: 488-493, 1987). Results of Monte-Carlo stimulation of photon propagation in the skin with a flat beam, $R=1$ cm are shown in Figure 3. Examples of diffuse reflectance $R\lambda$, attenuation coefficients $\alpha\lambda$ and penetration depths $d\lambda$ for some wavelengths are shown in Table 4. A schematic representation of the major optical pathways in human skin is shown in Figure 4.

Wavelength

Wavelength λ (nm) is the basic electromagnetic wave feature which is directly linked to the energy of an individual light quantum (photon). The more wavelength the less photon energy. Wavelength is also linked to the monochromatic light color. Visible monochromatic light changes its color with wavelength, increasing from violet and blue (shorter wavelengths) to orange and red (longer wavelengths). Cell culture experiments have indicated that there is a selectivity in photoinduced phenomena related to wavelengths. Experiments on

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different cell cultures (microbe and mammalian) have revealed the ranges of wavelengths (360-440nm, 630-680 nm. 740-760 nm) where photoinduced phenomena are observed (Karu, Health Physics, 56:691-704, 1989; Karu, *IEEE J. of Quantum Electronics*, QE23:1703-1717, 1987).

5 Photoeffect can be induced by monochromatic light, only in cases, where a cell contains photoacceptors, substances which are able to absorb monochromatic light of this particular wavelength. No photoinduced cell phenomena can be observed if there are no wavelength specific photoacceptors in a cell.

10 The following factors have to be taken into account when considering LEPT dosimetry for monochromatic light of a particular wavelength λ . The dose required for "photobiomodulation" strongly depends on the wavelength. In general, the longer the wavelength the more dose is required to induce photoeffect. For example, in
15 experiments on cell cultures, doses required for DNA synthesis stimulation are 10-100 times less with blue light ($\lambda = 404$ nm) than with red ($\lambda = 680$ nm) or near infrared ($\lambda = 760$ nm) light.

Wavelengths in the range of from 400 to 10,000 nm may be used for LEPT, preferably from 500 to 2,000, more preferably from 600 to 1,100,
20 most preferably from 600 to 700 nm and 800-1,100. There appears to be some optimal wavelength range to induce every particular photoeffect or healing phenomenon. For example, light having a wavelength of from 600 to 700, preferably from 630 - 680 nm, may be used for wound and ulcer healing. For chronic soft tissue pathology monochromatic light in
25 near infrared wavelength range (800-1,100) is more suitable.

Biotissue optical parameters (reflection, scattering, refraction, absorption and depth penetration) depend on wavelength. Therefore, light wavelength affects three-dimensional light distribution in biotissue. For example in a specific wavelength range, the longer wavelength the
30 more light penetration depth. The darker skin the more light

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absorption, therefore the dose for a black skin has to be less than for a white skin.

Monochromaticity (Bandwidth)

Light source is described by its spectrum, which shows the range
5 of wavelengths of the emitted light. Strictly monochromatic light source
is a source of radiation with exactly the same wavelengths. This is never
achieved in practice even with a laser. Every light source can be
described by its spectrum bandwidth $\Delta\lambda(\text{nm})$. The smaller the bandwidth
the more monochromaticity of the light source. The following
10 considerations are important in regards to light source
monochromaticity.

Biological objects became adapted to wide-band solar radiation
through evolution. Therefore, pronounced photoinduced phenomena
in living cells can be observed only under irradiation by a light source
15 with narrow enough bandwidth. The exact restrictions on light
bandwidth may differ for various biological objects.

Simultaneous irradiation by wide bandwidth and
monochromatic light can lead to decrease or even disappearance of
"photobiomodulation" effect. Therefore, it is recommended to provide
20 some LEPT treatments in a darkened room.

Difference in wavelengths emitted by optical source is leading to
dispersion in light reflection, scattering, refraction and absorption which
can affect three-dimensional light distribution and LEPT dosimetry.

Bandwidth of the optical source can affect optimal intensity and
25 dose values required to induce a particular healing phenomenon. The
full bandwidth of monochromatic light to activate healing phenomena
should not exceed 30-40 nm.

Selection of Optical Parameter Protocols for LEPT

Optical parameter protocols, may be established by combining
30 the above-noted parameters. Once established the protocols may be
entered and stored in the central microprocessor. A user of the apparatus

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can then select the appropriate protocol for the disorder to be treated. The clinical practitioner must examine the patient, establish diagnosis and the following particulars of tissue pathology:

(a) for musculoskeletal conditions:

- 5 (i) the stage of inflammatory process (acute, subacute inflammation, chronic inflammation with or without flare-up of preexisting pathological condition)
- (ii) localization of soft tissue affected areas, muscle spasm, tender and trigger points

10 (b) for skin conditions:

the stage of inflammatory process (acute or chronic inflammation, presence or absence of bacteria contamination)

LEPT optical parameters are chosen from Tables 1-3, 5-7, based on diagnosis and soft tissue condition.

15 Some suitable protocol ranges are shown in Table 7 below.

Table 7

Wavelength	Power	Beam Diameter or Covered Area Size	Intensity	Dose
Red	(1-40) mW	(0.1-15) cm	(1-220) mW/cm ²	(0.05-20) J/cm ²
Infrared	(10-200) mW	(0.1-15) cm	(1-1220) mW/cm ²	(0.5-150) J/cm ²

Intensity and dose are important parameters in providing the proper optical parameter protocols to induce photobiomodulation phenomena. The total volume and amount of cells exposed to LEPT depends on the light incident intensity and beam size.

Powers of optical sources used for LEPT differ by one order of magnitude and the rest of the parameters (treated area size, intensity and dose) differ by more than two orders of magnitude from each other.

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There are other optical parameters which can affect "photobiomodulation" phenomena. To be in a position to repeat particular *in vitro* or *in vivo* studies an investigator has carefully to reproduce the same experimental conditions. Failure to control properly all significant optical parameters may lead to nonreproducibility of results both in experiments and clinical trials.

Optical parameter protocols for various disorders were determined by the present inventors and examples of protocols are provided below (see Tables 8, 9 and 10). In Table 8, in the column entitled "Probe", R means red and IR means infrared, and the number refers to the number of optical sources used. Thus, for example, R-7 refers to a probe having 7 light emitting or superluminous diodes, each red. IR-LD means infrared laser or laser diode. Also in Table 8, the "frequency" refers to the light source being continuously on ("CW" - continuous wave mode) or pulsed, in which case the number given is the pulse repetition rate per second.

In Table 9, the "Protocol #" refers to the protocol number in Table 8. When the treatment consists of more than one protocol, they are administered sequentially, in the order shown, one immediately after the other.

Table 8

Examples of LEPT protocols for some musculoskeletal and dermatological conditions

Protocol #	Pathological condition	Probe	Wavelength (nm)	Frequency (Hz)	Single diode power (mW)	Exposure time (sec.)	Note
1	Chronic ulcers or wounds, stimulation of tissue repair	R-7 R-14 R-16 R-22	630-670	CW or 100	4-6 or 2-3	130-180 or 130-200	Hold the probe at the distance 7 cm directly over the ulcer surface
2	Chronic ulcers or wounds, a cute inflammatory condition, infected	R-7 R-14 R-16 R-22	630-670	CW or 100	4-6	130-200	Hold the probe in near contact to the ulcer surface
3	Chronic ulcers, improvement of microcirculation	IR-7 IR-14 IR-16 IR-22	800-1,100	10 or CW	6-12	20-40	Contact application on the skin surrounding the ulcer
4	Acute post-traumatic inflammation in soft tissue	R-7 R-14 R-16 R-22	630-700	CW or 100	4-6	180-400	Contact application over the affected area
5	Acute post-traumatic inflammation in soft tissue	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100	10-15	40-150	Contact application over the affected area

Protocol #	Pathological condition	Probe	Wavelength (nm)	Frequency (Hz)	Single diode power (mW)	Exposure time (sec.)	Note
6	Whiplash	R-7 R-14 R-16 R-22	630-700	CW or 100, 1.2	4-6	400-500	Moving the probe over spine area (C ₂ -T ₄) at the distance 7cm with the frequency 5 movements per minute
7	Whiplash	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	10-15	400-500	Moving the probe over spine area (C ₂ -T ₄) at the distance 1cm with the frequency 5 movements per minute
8	Chronic inflammation in soft tissue (flare-up stage), arthritis, degenerative disc disease, chronic tendinitis, etc.	R-7 R-14 R-16 R-22	630-700	CW or 100, 1.2	4-6	120-300	Hold the probe at the distance 7 cm over the affected area
9	Chronic inflammation in soft tissue (flare-up stage), arthritis, degenerative disc disease, chronic tendinitis, etc.	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	10-15	150-300	Hold the probe at the distance 1 cm over the affected area

Protocol #	Pathological condition	Probe	Wavelength (nm)	Frequency (Hz)	Single diode power (mW)	Exposure time (sec.)	Note
10	Chronic inflammation in soft tissue (no flare-up), arthritis, epicondylitis, chronic tendinitis, etc.	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	4 or 6.8 or 12	300-400 or 200-250 or 90-120	Hold the probe at the distance 0.2-0.3 cm over the affected area
11	Chronic inflammation in soft tissue (no flare-up), arthritis, epicondylitis, chronic tendinitis, etc.	IR-7 IR-14 IR-16 IR-22	800-1,100	100, 1.2	10-15	20-70	Contact, over the affected area
12	Chronic inflammation in soft tissue (no flare-up), arthritis, epicondylitis, chronic tendinitis, etc.	IR-LD	800-1,100	CW	50-200	3-30	Contact, selected points in the affected area
13	Muscle spasm relief	R-7 R-14 R-16 R-22	630-700	CW or 10 or 100, 1.2	4-6	120-300	Hold the probe at the distance 1 cm over the affected area
14	Muscle spasm relief	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 10 or 100, 1.2	10-15	120-300	Hold the probe at the distance 1 cm over the affected area

Protocol #	Pathological condition	Probe	Wavelength (nm)	Frequency (Hz)	Single diode power (mW)	Exposure time (sec.)	Note
15	Muscle spasm relief	IR-7 IR-14 IR-16 IR-22	800-1,100	100, 1.2	10-15	20-50	Contact, over the affected area
16	Muscle spasm relief	IR-LD	800-1,100	CW	50-200	3-20	Contact, selected points in the affected area
17	Carpal tunnel syndrome	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	10-15	120-300	Hold the probe at the distance 1 cm over the median nerve compression area
18	Carpal tunnel syndrome	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	10-15	30-120	Hold the probe at the distance 0.2-0.3 cm over the median nerve compression area
19	Carpal tunnel syndrome	IR-7 IR-14 IR-16 IR-22	800-1,100	4 or 100, 1.2	10-15	20-60	Contact, over the palm and the median nerve compression area

Protocol #	Pathological condition	Probe	Wavelength (nm)	Frequency (Hz)	Single diode power (mW)	Exposure time (sec.)	Note
20	Carpal tunnel syndrome	IR-1	800-1,100	CW or 100, 1.2	12-15	25-300	Contact, selected points in the arm, forearm, hand and points over the median nerve compression area
21	Carpal tunnel syndrome	IR-LD	800-1,100	CW	50-200	5-60	Contact, selected points in the arm, forearm, hand and points over the median nerve compression area
22	Neuritis, neuralgia, trigeminal neuralgia	IR-7 IR-14 IR-16 IR-22	800-1,100	CW or 100, 1.2	10-15	20-100	Hold the probe at the distance 1 cm over the affected area
23	Neuritis, neuralgia, trigeminal neuralgia, etc.	IR-7 IR-14 IR-16	800-1,100	100, 1.2	10-15	20-40	Contact, over the affected area
24	Neuritis, neuralgia, trigeminal neuralgia, etc.	IR-1	800-1,100	CW or 100, 1.2	10-15	25-160	Contact, selected points in the affected area
25	Neuritis, neuralgia, trigeminal neuralgia, etc.	IR-LD	800-1,100	CW	30-150	5-40	Contact, selected points in the affected area

Table 9

Examples of daily treatment schedule:

1. Chronic ulcers or wounds, acute inflammatory condition, infected*

Day	1	2	3	4	5	6*	7	8	9	10
Protocol #	2+1	2+1	2+1	2+1	2+1	1+3	1+3	1+3	1+3	1+3

2. Acute post-traumatic inflammation in soft tissue

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	4	4	4	4	5	5	5	5	5	5

* Administration of protocol #2 is discontinued after resolution of acute inflammation and infection.

3. Whiplash

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	6+7	6+7	6+7	6+7	6+7	6+7	6+7	6+7	6+7	6+7

Examples of daily treatment schedule (cntd.):

4. Chronic inflammation in soft tissue (flare-up stage)

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9	8 or 9

5. Chronic inflammation in soft tissue (no flare-up)

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	10	10	11	11	11+12	11+12	11+12	11+12	11+12	11+12

6. Muscle spasm relief

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	10 or 14	10 or 14	11 or 15	11 or 15	11+12	11+12	11+12	11+12	11+12	11+12

7. Carpal tunnel syndrome

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	17+20	17+20	18+20	18+20	19+20	19+20	19+21	19+21	19+21	19+21

Examples of daily treatment schedule (cntd.):

8. Neuritis, neuralgia, trigeminal neuralgia

Day	1	2	3	4	5	6	7	8	9	10
Protocol #	22+24	22+24	22+24	23+24	23+24	23+25	23+25	23+25	23+25	23+25

R-7, 14, 16, 22 - represent multiple light sources with $\lambda = 630\text{-}700\text{nm}$,
The light sources spacial distribution are shown on Fig. ...

IR-1 represents single monochromatic light source with $\lambda = 800\text{-}1,100\text{ nm}$
IR-7, 12, 14, 16, 22 - represent multiple light sources with $\lambda = 800\text{-}1,100\text{ nm}$
The light sources spacial distribution are shown on Fig. ...
(CW - continuous wave, 4, 10, 100 Hz are wave frequencies and 1.2 Hz is the modulation frequency for the above CW or other frequencies)

IR-LD represents laser or laser diode with $\lambda = 800\text{-}1,100\text{ nm}$

Table 10

		Axon				DNA & RNA					Membrane thickness
Biological structure size (cm)	0.1	0.01	0.003	0.001	3×10^{-4}	10^{-4}	3×10^{-5}	10^{-5}	3×10^{-6}	10^{-6}	
Pulse duration (sec)	10	0.1	0.01	0.001	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	

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Central Microprocessor

The selected optical parameter protocols may be stored in a central microprocessor, which may be powered by any standard electrical power source.

5 Figure 5 shows an illustrative relationship between dosage and intensity in three cases. Reference numeral 1 refers to the relationship between intensity and dosage which may be required for ulcer, wound healing, or smooth scar formation. Block 2 shows the required relationship for ulcer, wound healing in acute and sub acute conditions.
10 Block 3 shows a different relationship which may be required for infected wound healing. Block 4 shows the relationship between intensity and dosage provided by a typical laser, which as will be seen may completely miss the areas needed.

Base Unit and Probe

15 The selected optical parameter protocols may be stored in a central microprocessor of a base unit, which may be powered by any standard electrical power supply. The base unit may include a keypad for the user input interface and a display for the user output interface. The system contains a microprocessor and 8 kilobytes of non-volatile
20 memory which will normally hold all the optical parameter protocols needed.

 A typical base unit 8 is shown in Fig. 6 as having a keyboard 10 connected to a microcontroller 12 (a single chip) having an EPROM RAM memory 14. Circuit 16 provides the required clock signal. Information
25 entered from the keyboard is decoded and processed by microcontroller 12 and is instantly displayed and updated on a liquid crystal display module 18. The display has a backlight feature which is controlled by the microcontroller via circuit 20. The user can select the on/off state of the liquid crystal display module backlight from the keypad. Circuit 22 is a
30 digital potentiometer which provides contrast adjust by the user keypad via the microcontroller.

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The memory 14 is a 10 kilobyte serially interfaced EEPROM memory used to contain the protocol data for up to 1,000 protocols.

Battery level is monitored, and displayed on display module 18 by the microcontroller using R1, R2, C1 as a voltage mirror. The battery charge rate is fixed by R5. Diode D2 eliminates a voltage drop across R5 during normal operation. Diode D1 protects the entire circuit against incorrect polarity on the charger.

Visible or invisible light coming from the probes can be tested by phototransistor Q2. If the incoming light exceeds a preset threshold, set by V1, a display message on the display module 18 indicates that a present light signal exists on the probe unit.

Audio beeper 24 is used to provide acoustical feedback for event confirmation such as keystroke or low battery level. Capacitors C2, C3, and C5 to C8 provide noise decoupling and voltage stabilization for the circuit.

The protocols stored in the base unit shown in Fig. 6 may be transferred to wireless probe units (to be described) using output plug 26.

Wireless Probe Units

The wireless probe units receive the optical parameter protocols from the base unit and are used to apply LEPT to the patient. A typical wireless probe unit is shown at 40 in Fig. 7 and includes a microcontroller and timing circuit 42 clocked by a 4 MHz ceramic resonator 44. Microcontroller U2 is a single chip with EPROM program memory and suitable RAM. Capacitor C6 provides noise decoupling for the microcontroller.

Battery voltage monitoring and charging is performed once per second by the microcontroller with the help of R5, R6 and C7 as a battery voltage mirror and A1, A2 as power relays to provide connections/disconnections of the batteries to the input charge power. The battery voltage mirror is read by the microcontrollers' built-in analog to digital converter and is translated into battery charge before

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determining the on/off state of the relays A1, A2.

R4, C4 provide proper power on reset for the microcontroller boot start.

5 Audio beeper 48 provides an audio indication upon different events such as timer start, timer stop, low battery and the like.

Display 50 is a four digit alpha-numeric LED display which will show system parameters such as timer, power, frequency, unit serial number and the like.

10 Switch S1 is a momentary single pole, single throw switch used to start or stop the timer or initiate a complete system parameter display.

15 A software digital to analog pulse width modulated pulse generated on pin 2 of the microcontroller 42 is converted into an analog voltage by R7, C8. This voltage is then buffered by operational amplifier 54. The voltage is then conditioned by adjusting voltage V1 which operates in conjunction with R8 to establish a voltage divider circuit. The resultant voltage is fed to operational amplifier 56 which is part of the transconductance (voltage to current converter) amplifier generally indicated at 58.

20 Pulses sent to pin 2 of Q1-A by the microcontroller will control the frequency of the signal by switching the output power between on and off modes.

Circuit 60 is a 5 volt voltage regulator which provides power for the total circuit.

25 Jack 62 acts as a charger connection for the unit (to charge its battery) and also acts as the programming connection, to transfer protocols to the memory of microcontroller chip 42 from pin 26 of the base unit. When a charger is plugged in, the voltage at pin 1 of R3 goes high and informs the microcontroller 42 that the charger is plugged in. If the base unit programmer pin 26 is plugged in instead of the charger, a low voltage on pin 1 of R3 indicates the presence of the base unit programmer connection to jack 62. Diode D1 protects the circuit in the

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event of an incorrect polarity connection to jack 62.

In use, one central base unit may be used for a clinic, holding all of the required protocols. Individual users may have wireless probe units 40, which they will plug into the base unit 8 (Fig. 6). They will then
5 operate the keyboard on base unit 8 to transfer the required protocols to wireless probe 40 (see Fig. 7), after which they will take the wireless probe unit for treatment. As shown, the wireless probe 40 (Fig. 7) includes single or multiple laser or light emitting diodes 68 which are activated in the required sequence and combinations by the protocols stored in the
10 microcontroller 42 memory.

When a user of a probe unit wishes to change the protocols in the probe unit, he/she simply plugs the wireless unit into the base unit as described and operates the keypad 10 of the base unit 8 to modify or change the protocols which have been stored in the probe unit. Then,
15 when the probe unit is used (by operating switch S1), the lights sources 68 are suitably illuminated under control of the microcontroller and timer 42 to illuminate the area to be treated in accordance with the protocol or protocols stored in the wireless probe 40.

If desired, and as shown in Fig. 8, the probe unit may be a home
20 unit 70 which includes a modem (not shown) so that it can be programmed remotely by a telephone link 72 (which can include a satellite link), from the base unit 74 which itself operates via an interface unit or modem 76. Thus, customers with the home unit, in their far away locations, can call the location having the base unit and after
25 consulting with a therapist, they can have their home unit programmed for a selected period of operation time and power settings. Alternatively the protocols may be stored in an office computer 76 for transmission to the home unit. The therapist will then enter the desired protocol settings into the computer to be sent to the home unit 70, including the
30 length of time (e.g. one month) during which the home unit 70 is permitted to be operative (all controlled by the microcontroller 42 in the

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home unit). When the therapist enters a send command to the computer 76, protocol information is transferred to the home unit 70 via the telephone link 72. The remaining time of permitted use, previous protocol numbers and serial number information is sent from the home unit and displayed on the computer, utilizing the home unit microcontroller 42. The therapist can view this information and confirm the home unit's proper time and protocol settings. The computer 76 may be programmed to permit the therapist to keep track of all of the home units and enter his/her comments into the computer as the therapy progresses.

After data is sent by the therapist to the home unit 70 by telephone, the computer 76 may confirm the new data transferred by reading it back to the therapist after the transmission has been completed.

Two views of a typical home unit 70 are shown in Figs. 9 and 10. The home unit 70 is able to store four protocols (all programmable) and its face 80 has four LEDs 82 marked I, II, III and IV, to show which protocol has been selected. A single start/stop button or switch S2 will select the desired protocol, by keeping the switch S2 pressed for more than five seconds to step through the protocols and releasing it on the desired protocol number. The LEDs 82 marked I to IV will light in sequence as switch S2 steps the unit through the various protocols. The switch S2 will also start or stop the treatment by pressing it for less than five seconds and then releasing it. These operations are controlled by the microcontroller 42.

Each or all of the four protocols can be modified as mentioned using a computer and a telephone line, and each protocol can be disabled in the same manner.

The parameters in each protocol include:

Shut down timer: select from one of the following - 15 minutes to 30 hours in 15 minute intervals.

Power: Power can be selected from 1 to 12mW in 3 steps (4mW,

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8mW, 12mW) for IR LEDs and 0 to 6 mW in 3 steps (2mW, 4mW, 6mW) for Red LEDs.

Frequency: can be selected from Zero (CW) to 10 Hz in 1Hz steps and from 10 to 100 in 10 Hz steps.

5 Modulation Frequency: Can be turned on or off (Modulation freq. e.g. = 1.2 Hz).

Point timer: is a count down timer and can be selected from a range of Zero (Manual) to 600 seconds in 5 second intervals.

10 Probe type selection: Since each unit has a single IR and a multiple (14) red or multiple (14) IR, the selection is included in the protocol.

User Protocol Select Enable/Disable: Home unit can be set to enable or disable the user from selecting the protocols.

15 User Protocol Selection: Since each unit has 4 programmable (by phone) protocols, the user can select the desired protocol by pressing the start/stop button and scroll through the protocol (when button is released on desired protocol, indicated by one of the 4 LEDs, that protocol will be selected). If any one of the 4 protocols is disabled, it will not light up in the rotation. A maximum of 3 protocols only can be turned off
20 (one protocol must always be enabled).

The other face 84 of the home unit 70 contains 14 light sources (laser diodes) 68 arranged in three rows of five, four and five, so that appropriate patterns of illumination can be provided as required by the protocol selected. A single light source 68a is also provided, located in a
25 stalk 86 extending from the unit so that illumination can be provided using the single source 68a if required by the protocol selected.

Single optical sources are suitable for tender points, trigger points, selected points in the affected area, points on the skin overlying the treatment target (e.g. tendon, spur, calcification deposit), spinal nerve
30 roots, points on the skin overlying selected nerve pathways and other localized (e.g. acupuncture) points.

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Multiple optical source (cluster) probes may be used to stimulate affected area (e.g. joint, muscle, ulcer), selected dermatomes, skin overlying selected nerve pathways and reflexogenic zones (e.g. stimulation of the skin overlying carotid sinus with proper optical parameters can reduce elevated blood pressure).

Cluster probes are helpful to reduce treatment time and provide simultaneous three-dimensional treatment. Some LEPT applications are impossible without using cluster probes, because treatment time would otherwise be enormously long (for example, in the case of large ulcers). In addition, even more importantly, cluster probe application can lead in some cases to different physiological body responses compared to point by point stimulation. For example, cluster probe application provides much more pronounced anti-inflammatory and antiedematous effect for acute post-traumatic conditions compared to point by point stimulation. Cluster probe design has to be geared to provide the required three-dimensional light distribution within biotissue to produce the desired physiologic response and therapeutic effect.

Many different types of probes may be used for generating beams of light. If desired the optical source can be a white light source which provides a beam that can be collimated, focussed or defocussed by passing it through a lens and light of particular wavelength may be selected using filters. The beam may be directed to the tissue to be treated through variously shaped bodies with holes to permit passage of the light and to control the pattern of light delivered to the skin. The probe may be shaped to fit the body part to be treated. Examples of suitable probes are shown in Figs. 11A to 11F, which show a suitable probe having a five by seven matrix of optical diodes 68 illuminated in various patterns as required by the protocol selected.

Figs. 12A to 12F show an array 90 of optical diodes 68 arranged in a circular pattern. Again, different patterns of LEDs 68 are shown as illuminated, depending on the protocol selected.

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If desired, the probe may be constructed of flexible plastic or other suitable material as shown at 100 in Fig. 13, so that it can be wrapped around the surface contours of the body. The probe 100 may be secured in position by adhesive or VELCRO (trade mark) tape as required.

5 Cabling 102 and a plug 104 may be used to plug the flexible part 100 of the probe into the remainder of the probe unit which will contain the circuitry described for selecting and illuminating light sources 68 in the required pattern for the required lengths of time.

Alternatively, as shown in Fig. 14, a probe unit 106 may be formed in the shape of a ring, having light sources 68 arranged on its inner surface, to apply treatment to a finger. Different size rings may be made for different finger sizes, or an adjustment such as a spring (not shown) may be provided so that the ring will fit different size fingers.

10

Applying the beam of light to the biological tissue

There are different LEPT techniques depending on the application. In the contact technique, a probe (single or multiple source) is applied directly to the skin surface. In the contact with pressure technique, a probe is applied to the skin surface with pressure. This technique allows deeper light penetration to the tissue due to the following phenomena: light scattering is significantly less in compressed tissue and light absorption by blood is less because blood is partially squeezed out of the compressed biotissue.

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The non-contact technique can be used with both single or multiple source probes. The non-contact technique is used to increase the treated area size. For example, for big size ulcers, the non-contact technique allows to stimulate more ulcer and surrounding tissue surface improving therefore, healing effect; to decrease light intensity on the skin surface and increase simultaneously the treated area size, for example, to induce analgesic effects for tooth extraction specific acupuncture points could be stimulated by He-Ne laser at a distance of about 0.5 m (depending on the beam divergency) for minutes. The

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contact stimulation by laser with high intensity and short time exposure is not that effective for this purpose.

5 The scanning technique is used for the treatment of large areas with single or cluster probes. The probe is moved by the therapist or special scanning device along the skin surface with definite speed and the affected area is irradiated by a defocussed laser beam. This technique is used when the laser beam has very small divergence and the area to be treated is large. Defocussing lenses can be used to increase beam size and reduce light intensity. This technique could be used, for example, for the treatment of ulcers and skin dermatosis.

Method for stimulating healing of a disorder

15 As hereinbefore noted, the present invention provides a method for stimulating healing of a disorder of a biological tissue in a mammal by stimulating the tissue with light having the selected optical parameters as discussed above. Although not wishing to be bound by any particular mode of action, a brief discussion follows of some possible mechanisms of the healing action of LEPT having the selected optical parameters.

20 At the biomolecular level, LEPT induces changes in the levels of enzymatic activity, including activation of the enzymes of the respiratory chain and of Na, K ATPases. LEPT also induces synthesis of DNA, RNA, ATP and proteins, such as collagen, and alters the levels of cAMP in the cells. At the cellular level, LEPT activates cell metabolism and respiration and secretory activity, such as mast cell degranulation. Cell motility may also be enhanced in motile cells, such as keratinocytes and spermatozoa. Transmembrane transport alterations and cell permeability changes may also result in alterations in intracellular and extracellular ion concentrations. LEPT may also modulate the release of cell cytokines, such as $\beta 2$ transforming growth factor and platelet derived growth factor.

30 At the tissue level, LEPT may cause vasodilation, vasoconstriction, anastomosis opening, angiogenesis, blood vessel

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permeability changes, wound granulation, epithelization activation, skin collagen content and tensile strength increase, increase in mast cell count and degranulation, increase nerve action potential, stimulation of regeneration of damaged nerve tissue and acceleration of bone fracture consolidation.

At the systemic level, LEPT treatment may improve microcirculation in the targeted area, increase lymph flow and lymphatic drainage and result in faster resolution of post traumatic hematoma and edema. LEPT may also exert specific and non-specific effects on the immune system by affecting phagocytosis activation, modulation of reactive oxygen species release by neutrophilic granulocytes, neutrophil chemotaxis enhancement, T-lymphocyte blast transformation, T-Rosette formation activation, killer cell activation and alteration in blood levels of complement and immunoglobulins, including IgA, IgG and IgM. LEPT may also influence the hemopoietic system by increasing the counts of red and white blood cells, including lymphocytes and polymorphonuclear leukocytes and of hemoglobin. LEPT may also exert the following effects: increase in blood protein, alteration in prostaglandin level, decrease in blood viscosity and activation of the blood antioxidant system by influencing levels of catalase, superoxide-dismutase and ceruloplasmin. LEPT may also decrease the erythrocyte sedimentation rate in patients with rheumatoid arthritis. LEPT may further have the following therapeutic effects: antiinflammatory, antiedematous, immunomodulative, microcirculation improvement in precisely targeted areas, soft tissue regeneration acceleration, bone fracture consolidation acceleration and muscle spasm relaxation.

The optical parameter protocols of the treatment may be derived based on the biological tissue or cells size to be treated. The appropriate pulse duration based on the size of the biological structure to be targeted is shown in Table 10.

The method and apparatus of maximal temperature and

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pressure gradients are generated within biological structures of various sizes by pulsed electromagnetic waves of properly selected wavelength and pulse duration.

5 To produce an energy gradient within the target biological structure while its electromagnetic wave is propagating through the structure, the following conditions are required:

1. The target biological structure (e.g. vessels, nerve, cell, membrane, mitochondrion, etc.) has to have
 - (a) increased electromagnetic wave absorbtion coefficient for
10 definite wavelength (lengths) comparing to the surrounding tissue,
 - (b) or decreased specific heat comparing to the surrounding tissue,
 - (c) or combination of the conditions a) and b).

15 Notice: condition a) may be created in target biological structure artificially by introduction of photosensitizer which is selectively bound to this biological structure and has high light absorbtion coefficient for the definite wavelength Ω_o .

2. The maximal energy gradient in the target biological
20 structure of size ℓ and with the maximum light absorbtion coefficient (comparing with surrounding tissue for wavelength Ω_o , will be provided by pulsed electromagnetic wave irradiation with narrow band around wavelength Ω_o and pulse duration T_o equal to $T_o = \ell^2/D$ where $D(\text{cm}^2/\text{sec})$ is the thermal diffusion constant of surrounding tissue.

25 The following non-limiting examples are illustrative of the present invention:

EXAMPLES

EXAMPLE 1

Chronic Leg Ulcers

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Fifty patients with infected or non-infected chronic leg ulcers, which had failed to respond to conventional therapy for more than 10 weeks, were treated by LEPT. The chronic leg ulcers were of different etiology and included venous ulcers, diabetic ulcers, decubitus ulcers, burns and post-traumatic ulcers. A combination of protocols 1 and 3 (Table 8) was used for non-infected wounds and a combination of protocols 1 and 2 (Table 8) was used for infected wounds. Following LEPT treatment, 40 of the ulcers (80 %) were completely healed, 5 ulcers (10 %) were reduced in size and 5 ulcers (10 %) were unchanged.

Twenty four patients with 32 infected or non-infected ulcers of various etiology (venous ulcers, diabetic ulcers, decubitus ulcers, post-traumatic ulcers, etc.), which had failed to respond to conventional therapy, were treated by LEPT. Conventional therapy was the same for all three groups of patients and included cleansing with saline, application of wet-to-dry dressing followed by a kling. Total of 15 patients with 18 ulcers were treated with real LEPT, 5 patients with 10 ulcers received placebo LEPT and 4 patients with 4 ulcers received conventional therapy only. Placebo LEPT was provided with the LEPT device looking identical to a real LEPT, however it was producing no output optical parameters. Neither the patient nor the personnel involved in the study were aware of the treatment area the patient was in. This methodology completely satisfied double-blind study requirement. After 10 weeks of treatment the total ulcer size decrease in the real LEPT group was 79.4%, in the placebo group total ulcer size decrease was 31.9% from baseline, and in the control group (conventional therapy only) 45.8% total ulcer size decrease from baseline.

A comparison of the results obtained in the present study with those previously obtained by others using conventional therapy or low energy laser therapy are shown in Table 11, which illustrates the superior results obtained with the LEPT treatment of the present invention.

64 year-old patient, female, presented with the leg ulcer of post-

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traumatic origin and venous insufficiency. The first onset of the ulcer was 45 years ago after a car accident. The patient had three attempts at skin grafts which had failed. The patient did not allow another surgery. Allergy to antibiotics and to some dressings, severe pain and inflammation developed.

The ulcer's size was 3.9 cm². The patient received LEPT treatments with the following protocol: IR-7-probe, 880 nm, 12 mW, 10 Hz, modulation frequency 1.2 Hz, 25 sec contact on the skin surrounding ulcer and R-22 probe, 660 nm, 6 mW, CW, for 180 s at the distance 7 cm over the ulcer area. After three courses of LEPT (60 treatments total) the ulcer healed completely.

EXAMPLE 2

Carpal Tunnel Syndrome

Twenty one patients with carpal tunnel syndrome who had been receiving conventional therapy were treated with LEPT three times a week for five weeks. A combination of protocols 8, 19 and 20 (Table 8) was used. Conventional therapy included wrist immobilization at night, specific chiropractic manipulations and vitamins C, E and B₆. No corticosteroid injections during the course of LEPT were applied. Fifteen patients (71.4 %) were free of symptoms and had returned to work after treatment. These patients remained free of symptoms after 3-6-18 months of follow up examinations. Two patients (9.5 %) had reduced symptoms and 4 patients (19.1%) did not respond.

A comparison of the results obtained in the present study with those previously obtained by others using conventional therapy or low energy laser therapy are shown in Table 12, which illustrates the superior results obtained with the LEPT treatment of the present invention.

EXAMPLE 3

Acute Whiplash Injury

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Fifty four patients with acute whiplash injury were randomly assigned to three groups. Group 1 (17 patients) received manipulation therapy (MT), Group 2 (18 patients) received MT plus exercise and Group 3 (19 patients) received MT, exercise and LEPT (protocols 6 and 7, Table 8) were administered three times a week for eight weeks. In both protocols 100 Hz frequency and 1.2 Hz modulation frequency were used.

Analysis of variance (ANOVA) was used to test if the patients were properly randomized prior to the study. ANOVA test did not reveal any statistically significant difference between 3 groups in the extensor neck muscle strength (EMS) and uninterrupted sleep (US) at night prior to the study.

The Newman-Keuls' multiple-range test was used to obtain more complete and accurate analysis of data obtained after the course of therapy.

The Newman-Keuls' test revealed statistically significant improvement (SS) in both, EMS and US parameters measured in Group 3 vs. Group 1 and SS improvement in US in Group 3 vs. Group 2. The Newman-Keuls' test did not reveal any SS improvement in US in Group 1 during the course. In Group 2 SS improvement was first observed only after 8 weeks of therapy. In Group 3 SS improvement in EMS was observed much earlier: after 4 weeks of therapy. (See Table 13.)

EXAMPLE 4

Acute and chronic musculoskeletal conditions

Patients having a range of acute and chronic musculoskeletal conditions were treated by LEPT according to the protocol of the invention as described herein. Most of the patients treated had failed to respond earlier to conventional treatments such as pharmacotherapy and physiotherapy using heat, transcutaneous nerve stimulation, interferential and ultrasound. One hundred ninety nine patients received a course of LEPT. LEPT treatment provided significant

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improvement of 60-85% of musculoskeletal conditions.

Eighty five patients with osteoarthritis were treated with LEPT (protocols 8-10, Table 8), of these patients, 59 showed significant improvement and 5 showed some improvement.

5 Fifty patients with low back pain were treated with LEPT (protocols 8, 11, 13, 24, Table 8), of these patients, 39 were free of symptoms or showed significant improvement and 5 showed some improvement.

10 Seventy three patients with degenerative disc disease were treated with LEPT (protocols 8, 11, 13, 24, Table 8), of these patients, 44 showed significant improvement.

 Thirty two patients with tension headache and neck pain were treated with LEPT (protocols 13, 14, 15, 24, Table 8), of these patients, 24 showed significant improvement and 2 showed some improvement.

15 Twenty patients with spurs were treated with LEPT (protocol 15, Table 8), of these patients, 17 were free of symptoms.

 The results from the above-noted LEPT treatments are summarized in Table 14.

Examples of case histories are provided below.

20 Female, age 39-Acute left shoulder capsulitis: abduction increased 15° after the first treatment with 60% decrease in pain. Abduction increased to 90° following second treatment. Following three LEPT treatments (protocols 8, 14, 24, Table 8) abduction almost normal, pain minimal and no further treatment required.

25 Male, age 37- Acute right medial collateral ligament strain: after one LEPT treatment (protocols 4, 5, Table 8) was able to resume playing hockey and following two additional LEPT treatments patient was completely pain free and totally able to resume all normal activity.

30 Male, age 55 three year old rotator cuff tear, which was aggravated by swimming and golf: Had surgery contemplated and

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utilized cortisone injections, anti-inflammatory and analgesic medications. Pain free and full range of motion following five LEPT treatments (protocols 8, 9, 11, 24, Table 8).

5 Male, age 74 developed decreased flexion of right elbow. He stopped playing tennis, could not bring a cup of tea to his lips, or shave his neck. X-rays showed a spur on the proximal tip of the radius. After 24 LEPT treatments (protocols 11, 24, Table 8) and manipulation, X-rays showed a spur of 1/3 the original size. Patient could now raise a cup of tea for drinking, able to shave and returned to playing tennis. Follow-up 10 18 months examination revealed that the patient was still free of symptoms.

Female, age 31 years with rheumatoid arthritis for 10 years, had generalized stiffness, with aches and pains. She came into the clinic with a walking cane. Forward flexion of her body showed 'finger to floor' was 15 24", and it took her 15 minutes to climb the subway stairs. After 15 consecutive LEPT treatments (protocols 8, 9, 10, 11, Table 8) and manipulative therapy, she no longer uses the cane, 'finger to floor' is 6" and she is up the subway stairs in 5 minutes.

Female, age 41 with chronic cervical degenerative disc and joint 20 disease along with pain for 15 years. After 15 consecutive LEPT treatments (protocols 6, 7, 11, 24, Table 8), manipulative therapy and specific neck exercises, she no longer experiences pain, has increased motion, sleeps better and smokes 50% fewer cigarettes per day. Modulation frequency 1.2 Hz in CW mode was used in protocols 6 and 7.

25 Male, age 42 with chronic low back pain and radiation into the left hamstring and popliteal muscles. MIR studies indicated a mild disc bulge at L4-L5. After 8 consecutive LEPT treatments (protocols 13-15, 24, Table 8), manipulative therapy and specific exercises, patient has returned to jogging without pain, radiation or stiffness, and has increased 30 range of movement.

Female, age 71 year complained of severe knee pain with

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frequent episodes of swelling, causing her to be practically immobile. She was able to trace back her knee problem as having begun at age 51 and could recall only a few periods of remission, lasting no longer than three weeks, after having received steroid injection. Functional inquiry
5 indicated episodes of frequent abdominal pain (very sensitive to weather changes) and back pain which, on their own, she felt she would have been able to tolerate. However, in conjunction with the knee pain, she was not able to tolerate these symptoms. Her past history indicated that she had good health until age 50, it was later found that she has
10 polyolithiasis, for which she had not been operated on. She also has a tendency towards constipation and epigastric pain. She suffers from arteriosclerotic heart disease, with stable angina pectoris, and is on multi-pharmacy treatment. In addition, she is constantly taking different types of non-steroid anti-inflammatories. Musculoskeletal examination
15 revealed the presence of moderate varus alignment of the knees, of at least 7-10 degrees. There was moderate joint effusion in the left knee, with significant patellofemoral and medial joint compartment crepitation, on the left more so than on the right. X-ray showed considerable osteoarthritis changes involving both knees.

20 The patient underwent 12 LEPT treatments (protocols 8, 9, 10, 11, Table 8). During and after treatment, the patient was able to report a decrease in the frequency of her non-steroid anti-inflammatory intake, and said that she had remained free of severe knee pain for the past 1 1/2 months.

25 Male, 70 year old complained of right shoulder pain, which had become particularly bothersome over the past few weeks, and which had begun depriving him of adequate sleep. The patient stated that the pain had developed gradually over the last three months, and that it had not been responding to conventional physiotherapeutic treatment
30 modalities, using heat and TNS. Interferential treatment had also failed to improve his condition. The patient was unable to tolerate anti-

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inflammatory drugs because of gastrointestinal upset. He stated that, using potent analgesics such as Tylenol #3, he was only able to sleep for short periods. The patient mentioned that in the past he had experienced a few similar-type episodes affecting the right shoulder, but that these had always been easily controlled by means of conventional physiotherapy treatment. Examination of ranges of right shoulder movement showed significant decrease. In particular, abduction was approximately 70 degrees, and external rotation, with elbow flexed, was no more than 5 degrees. He had pain and tenderness over the rotator cuff area, with clicks and crepitation on external rotation. X-rays of the cervical spine and left shoulder were not contributory and, in particular, there was no calcification present. The patient was treated as suffering from right rotator cuff tendinitis.

He obtained 10 LEPT treatments (protocols 8, 9, 10, 11, 24, Table 8), and was able to report a significant improvement in his level of pain, as well as an improvement in his sleep pattern, which began developing gradually following the third LEPT treatment.

Female, 47 year old Esthetician, came to the doctor's office complaining of right heel pain, which was particularly bothersome in the mornings when the heel had to support the full pressure of her body weight. The patient stated that this problem had developed gradually over the preceding six to seven months. The patient was diagnosed to be suffering from plantar tendinitis and was treated by means of conventional modalities, such as ultrasound, heat, and steroid injections to the heel, all of which failed to achieve appropriate results. Her past history revealed that she suffers from peptic ulcer disease and is, therefore, unable to tolerate any non-steroid anti-inflammatory medication. Examination showed no neurological deficit present. There was localized pain on the middle of the heel.

The patient reported a significant improvement on her fourth LEPT treatment session (protocols 11, 24, Table 8) and after 10 treatments

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her pain had disappeared completely.

Male, 43 year old with chronic neck stiffness, decreased range of movement and intermittent radiation into the right biceps. After 15 LEPT treatments (protocols 13-15, 24, Table 8), manipulative therapy and specific neck exercises he has no longer neck stiffness, increased range of movement and no radiation into the right biceps. He also sleeps better.

Female, 43 year old with chronic low back pain and burning sensation in her feet-"feels like I am walking on hot coals". After 10 treatments of LEPT (protocols 13-15, 24, Table 8) and manipulative therapy, she is experiencing a 50% decrease in both her low back pain and the burning sensation in her feet. She reports also that she is walking nearly normally.

Male, 25 year old, diagnosed with bursitis in the sub deltoid bursa for the past year, resulting in decreased range of motion, inflammation and pain. Treatment strategy was implemented and after a full course of LEPT treatments (protocols 4, 11, 24, Table 8), patient retained complete range of motion, experienced no further inflammation or pain.

EXAMPLE 5

Post-Surgical Complications

More than 100 patients having a range of post-surgical complications, such as swelling, scars, were treated by LEPT according to the protocol of the invention as described herein. LEPT treatment resulted in faster resolution of post-surgical complications, smooth and tender scar formation and improvement of old scar tenderness, elasticity and softness.

Examples of case histories are provided below.

Male, age 47 - two previous laminectomies and surgeon hesitant

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regarding a third: Patient was reduced to a level of an invalid with constant left thigh pain and severe walking limitations. Following ten LEPT treatments (protocols 8-11, 24, Table 8), patient was able to stand normally and walked relatively normally with diminished pain by 60%.

5 Female, age 24 suffered chronic headaches and dizziness. As a child she had TMJ surgery to control her headaches. After 8 consecutive treatments of LEPT (protocols 22-24, Table 8), manipulative therapy and specific upper cervical exercises, she no longer experiences headaches and dizziness. She sleeps better and has more energy in the day.

10 Male, surgical face lift which did not take well. There was a tremendous amount of swelling and redness around the neck area of the scar. He has completed 6 LEPT treatments (protocols 4-5, Table 8), and the swelling-has significantly subsided, the redness has disappeared and the scar healing has taken effect, and is hardly noticeable.

15 **EXAMPLE 6**

Acute trauma and chronic post-traumatic conditions in the soft tissues and bones

20 One hundred twenty patients having a range of acute trauma and chronic post-traumatic conditions in the soft tissues and bones were treated by LEPT according to the protocol of the invention as described herein. Conditions treated include post-traumatic conditions in muscles, ligaments, joints, bones, etc. such as whiplash, sprains, strains and sport injuries in the foot, ankle, leg, knee, neck, shoulder and elbow. LEPT treatments were administered in accordance with protocols 4, 5 (Table 8)

25 at acute stage followed by protocols 8, 11, 24 (Table 8) for subacute stage of post-traumatic conditions.

30 Treatment with LEPT resulted in fast resolution of swelling, hematoma, inflammation and pain and accelerated regeneration of injured soft tissue, bone fracture consolidation, soft scar formation, muscle function and general recovery. Examples of case histories are

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provided below.

Female, multiple injuries, car ran over her. Back sprain, knee swelling. After treating her 2 x week with LEPT for a period of 4 weeks, she is 85% recovered. Before starting LEPT MD wanted to operate on
5 knee to remove calcium build-up causing immobility. Now she can walk and has significant movement in knee, the surgery has been put off.

Male, 33 year old with severe lacerations on hand. Extension palmar branch of ulnar nerves damage, patient unable to flex or grip with hand. Before completion of full course of LEPT treatments patient
10 had significant improvement in grip and flex abilities, no pain or inflammation was apparent. Patient discontinued treatment.

Crushed hand injury from job accident. Fracture of the metacarpal bone. Extreme swelling, edema and pain, suggested treatment was to surgical incise hand to alleviate extreme edema and
15 inflammation. LEPT treatment was offered and after first treatment 85% of swelling subsided, pain was almost completely diminished. Patient returned to work the next day. After 3 LEPT treatments condition was under control.

Non-Union of the Tibia- After 21-22 LEPT treatments, re X-ray
20 was performed. No change in bone fusion noted. However, soft tissue was completely healed and pain was substantially reduced.

Gun Shot Wound- A wound inflicted in the web space of hand between thumb and index finger. Conventional therapy failed to improve severe swelling, deep, open wound of 1/4 inch, tremendous
25 pain and slight infection. After first LEPT treatment swelling had subsided, inflamed area was greatly reduced and cicatrising had commenced. By 4 LEPT treatment the total wound was closed and normal healing was underway.

Female, age 46- Low back pain injury 2 1/2 years ago: in constant
30 pain and specialists contemplating surgery. Patient had difficulty walking, sitting and sleeping. After 8 LEPT treatments pain free and able

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to engage in normal activity with minimal pain.

Male, 44 years had a history of 3 whiplash injuries 13 years ago. Presently has left cervical pain with radiation into left shoulder and headaches. X-rays showed moderate degeneration of the C5-6 disc with a
5 straight cervical spine. After 15 LEPT treatments and specific exercises, patient has no headaches, no cervical pain or radiation and increased ability to sleep. X-rays showed a return to the normal lordotic cervical curve.

Female, 56 year old who operates a Ballet School, in addition to
10 teaching ballet. She complained of severe back pain, which she had developed suddenly after bending forcefully while still trying to retrieve something from the floor. Over the next few days, her back pain deteriorated further, to the point where she required assistance in order to even dress herself. Analgesic and myorelaxants failed to help her. The
15 patient was desperate to return to work for fear of losing her business. She was advised to immediate LEPT therapy. On examination ten days after the onset of symptoms, she still appeared to be in acute distress, as she required help in order to get up out of the chair and onto the examining table. On examination her range of back movement were
20 significantly reduced, as she was hardly able to reach to the knees on flexion. She had pain and tenderness over the lower paravertebral muscle group. The patient's response to LEPT therapy was immediate, with a gradual improvement in pain level and ranges of back movement after 12 treatments. A two week observation period following treatment,
25 indicated that the patient was free of symptoms.

Male, 41 year old was referred to Toronto Chiropractor Clinic. He had two motor vehicle accidents- "hyperextension whiplash injuries", the last being 12 years ago. At consultation, patient was experiencing neck pain on the left side with low grade radiation into the
30 left biceps. This condition was of permanent nature. Under strenuous activities such as gardening or carrying heavy grocery bags on the side,

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the radiation would progress to his left hand and index finger. Physical examination revealed normal reflexes and grip strength. The flexor-extensor neck strength ratio was inappropriate, whereby the flexor strength had increased compared to the extensor. X-rays showed that the cervical spine had lost its normal lordotic curve. There was also degenerative changes at C5C6. The course consisted of 15 LEPT treatments to the posterior and left lateral cervical spine, 3x week. A few sessions were missed, so that the total course duration was six weeks. The special exercises were done 5x week at nights before bed. After the course of LEPT and exercises the patient was free of symptoms. Re X-rays showed that the patient's cervical lordosis became close to normal. Follow-up 18 months examination revealed that the patient continued to do exercise and was free of symptoms.

EXAMPLE 7

Repetitive strain injuries

Patients having a range of repetitive strain injuries were treated by LEPT according to the protocol of the invention as described herein.

Male, 43 years old with history of 'carpal tunnel' symptoms for one year. After 4 treatments with the LEPT (protocols 17-20, Table 8) and specific manipulation of the wrist, he no longer suffers with these symptoms.

Male, 66 year old was presented with bilateral wrist pain. He had previously consulted an orthopedic surgeon and was booked for bilateral surgical release of the median nerve for carpal tunnel syndrome. The patient works in a dental lab and is required to perform repeated movements of the wrist and forearm while pinching and grasping small instruments. He first noticed pain in the wrists and thumb while riding his motorcycle. This progressed to pain and numbness while sleeping which awakened him. Relief was achieved by shaking the hands. Finally, he was unable to perform his job adequately as his grip was too weak.

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The patient was undergoing treatment for low back pain when he informed me of his wrist pain and forthcoming surgery. We discussed LEPT therapy for his carpal tunnel syndrome and treatments began immediately.

5 The diagnosis was based on patient history, the nerve conduction and EMG studies done by the orthopedic surgeon. In addition, the Phalens test and Tinels sign were positive and reproduced pain along the median nerve. There was bilateral atrophy of thenar eminence. Therapy included LEPT 3x week, vit. C, vit. E, vit. B6
10 supplementation, also the patient was instructed to wear wrist braces to immobilize the wrists at night. Specific chiropractic manipulation was carried out on dyskinetic joint of the wrists, elbow and neck as required. Soft tissue therapy included trigger point therapy along the forearm wrist flexor muscles and myofascial release, as required. Complete resolution
15 of the symptoms was achieved after 35 LEPT treatments (protocols 17-20, Table 8). The surgery was cancelled and there has been no reoccurrence to date, 15 months following the end of treatment.

EXAMPLE 8

Neurological and neuromuscular conditions

20 Patients having a range of neurological and neuromuscular conditions were treated by LEPT according to the protocol of the invention as described herein.

 Female, 51 year old who works as a medical secretary, complained of the spontaneous onset of numbness and a tingling
25 sensation involving the left hand. Shortly after, these symptoms settled into the inner border of the left forearm, and the fourth and fifth digits of the left hand. Her functional inquiry was unremarkable. Prior to this development she has been in a good health. Objectively, the patient was free of any neurological deficit, and in particular, was found to have no
30 organic pathology present in the distribution of the medial or ulnar

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5 nerves. The patient was seen by a orthopedic surgeon and a neurologist,
as well as by a rehabilitation medicine specialist, all of whom agreed that
there were no objective findings, compatible with nerve degeneration,
present. This was substantiated by X-ray examination as well as by EMG
studies. All the specialists agreed that the patient was suffering from left
ulnar neuropathy. Initially, the patient was treated by means of TNS,
analgesics, and vitamins, for a period of four weeks, displaying very little
improvement in her symptoms. Ten LEPT treatments (protocols 21-24,
Table 8) have proven to be successful, as following the LEPT therapy the
10 patient has been asymptomatic for the last two months.

EXAMPLE 9

Dermatological conditions

15 Patients having a range of dermatological conditions were
treated by LEPT according to the protocol of the invention as described
herein.

The patient with chronic ulcers were treated in accordance with
protocols 1-3, Table 8, depending on the ulcer condition (infected, acute
inflammatory condition or non-infected ulceration).

20 47 year old patient, diabetic-had bilateral toe amputation
followed by skin grafting. Skin graft healed slowly and 3 ulcers developed
on both feet which did not respond to any conventional therapy. After
the first course of 19 LEPT sessions administered for 2 out of 3 ulcers (3x
week) 1 ulcer healed and 1 improved. After the second course of 29 LEPT
treatments all ulcers healed.

25 65 year old female presented with 2 ulcers: L tibial ulcer which
persisted for 3 years and right distal tibial ulcer which did not heal for 1
year. There were 3 skin grafts attempts over the years and all failed. The
patient complained of burning sensation around all ulcers that kept her
up at night. After 6 LEPT treatments (3x week) she was able to expose
30 ulcers to air without pain. After 8-10 treatments her night pain was

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markedly reduced. Her right tibial ulcer healed after 30 sessions of LEPT and left tibial ulcer healed after 48 sessions of LEPT. Six months follow-up the patient is free of ulceration.

5 73 year old patient, male presented with 35 cm² ulcer on his big toe and adjacent foot area. The ulcer did not respond to conventional therapy for more than 3 months and was heavily bacteria-contaminated and had a lot of necrotic tissue. LEPT treatments were provided 3x week. After 20 LEPT treatments ulcer decreased in size by 50% and the patient had 2 weeks interval in LEPT. After this interval in LEPT 2 new
10 breakdown areas developed on the same foot. LEPT treatments were resumed on all 3 ulcers, 3x week. After total 42 LEPT treatments all ulcers completely healed. At the 14 months follow-up the patient is still free of ulceration.

15 60 year old female was admitted to Hospital burn-unit with burns 20 cm² to the right foot, scalded by hot tea. Burn was infected and did not respond to antibiotic treatment and daily cleaning for 3 weeks. Plastic surgeon intended to do skin grafts, but decided to try LEPT first. The patient was treated daily (5x week). After 14 sessions burns completely healed.

20 96 year old female with pressure ulcer 3 cm diameter on heel which did not heal for 1 year. Plastic surgeon tried to close the defect but skin graft broke down. Patient was being treated with dressings but they did not help. Patient complained of pain and was taking 3-4 Tylenol #3 daily. Patient received 10 consecutive LEPT treatments. After 10
25 treatments pain medications reduced to 1-2 Tylenol #1 tablets per day. After 25 treatments (5 weeks) ulcer healed.

 Female, 77 year old presented with mixed arteriovenous etiology ulcer on the right foot more than 200 cm². The ulcer onset happened in 1976 and had been open since then with occasional closing.
30 This ulcer persisted growing in size and became bacteria-contaminated despite different dressings and antibiotics used. The underlying causes of

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this ulcer was venous insufficiency, ischemia and osteomyelitis. Three previous skin grafts failed. Recently, the patient developed allergy to some dressings. Besides ulcer history, patient had in 1986 hysterectomy followed by radiation therapy after being diagnosed with adenocarcinoma uteri. The course of LEPT started at the end of Sept.'93. The LEPT therapy was provided 2-3 x week. The ulcer remained bacteria-free for a few months (~55 treatments) and size decreased by 50% and a bridge of new skin formed on the anterior part of the right foot separated one huge into 2 smaller ulcers. Taking into account the patient's age, nutritional status, failed skin grafts, bacteria contamination of the wound prior our treatment commencement the decrease in size by 50% was a major achievement.

Female, 82 years old had 2 venous stasis ulcers for about 2 months prior to receiving LEPT. During this period, nurses were visiting her for about 3x week for dressing changes with the wound showing little or no healing. Nursing visits were reduced after starting LEPT, although continued to monitor other health problems. The wounds (the largest approximately 1.5 cm in diameter) after initiating LEPT were healed following 27 sessions over 9 weeks. The staff also noted improved color in the affected limb after only a few treatments. The lady also had cellulitis, dementia and anemia. Although this case was difficult with other aspects of home-care, the compliance with LEPT treatments was total.

57 year old diabetic patient had a 2 cm in diameter ulcer on the metatarsal head of his left foot. He had a history of ulcers over a period of 10 years with his diabetes. In late November he was admitted to DECH with cellulitis and received surgical debridement of this current ulcer. EMII nurses began following him in mid December for IV therapy and dressing changes, with the wound showing only limited or no healing by mid March. He also had peripheral neuropathy, hypertension and nephropathy. After 30 LEPT treatments, this wound had closed. Nurses

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originally were visiting 3x week diminishing to only 1x week as IV therapy discontinued and patient was managing own dressing changes at the time LEPT started. These visits were discontinued shortly after as the physiotherapist carried out the care required.

5 Female, 58 years old with Multiple Sclerosis had two wounds (2 cm and 1 cm in diameter) in her coccygeal region for over two years. The wounds showed little success in healing. Nurses had been visiting 2-3x week since mid Nov.'93 but this had decreased to 1x week in Feb.'93. The lady was paraplegic with decreased sensation in her lower limbs. The
10 wounds were due to friction resulting from inefficient transfers. 28 LEPT treatments were given over a 9 1/2 week period, resulting in closure of both wounds.

 A 48 year old female had been suffering from herpes simplex attacks on her lips, for 30 years. These attacks were especially frequent in
15 a cold time of year and under stressful conditions. Painful herpes simplex lesions did not respond to any conventional therapy and usually it took from 9 to 15 days for a lesion to get healed. Low Energy Photon Therapy with a dose 8J/cm² and a wavelength of 660 nm was used to treat the lesion locally. The patient experienced immediate pain relief
20 and lesion became dry within 1-2 days after the first treatment. One to three LEPT treatments were enough to reduce lesion healing time to 3 to 6 days. The next lesion never appeared again at the spot previously treated by LEPT. The patient successfully used a home LEPT unit to treat herpes simplex lesion early on the lesion onset and to prevent lesion
25 development as well during one year. For three years follow-up after the last LEPT course the patient did not have any herpes simplex attacks.

 Tables 11, 12, 13 and 14 which follow show comparative analysis of LEPT versus conventional therapy for skin ulcers, carpal tunnel syndrome, and acute whiplash injury respectively, as well as a summary
30 of LEPT results which have been achieved to date. In addition, the information given in the appended claims is hereby incorporated into

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the disclosure.

Table 11
Comparative analysis of LEPT/LLLT/conventional therapy efficacy for skin ulcers

Condition	Efficacy of ulcer healing		
	LEPT (IMI Inc.) product	LLLT	Conventional Therapy
Infected & non-infected venous leg ulcers	<p>86% at SGH, Toronto</p> <p><u>Note:</u> 86% out of 22 chronic ulcers which didn't respond to CT healed after the course of LEPT (9 week average)¹</p>	<p>No SS difference</p> <p><u>Note:</u> 46 pts. were treated in two groups by real & placebo LLLT (for 12 weeks)².</p>	<p>33.3%</p> <p><u>Note:</u> Conventional therapy included cleansing with saline, application of paste bandage, followed by a support bandage plus exercise program - only 3 out of 9 ulcers healed after 12 weeks of CT².</p>
	<p>93% at EMH, Fredericton SS p<0.001</p> <p><u>Note:</u> 11 ulcers out of 18 healed completely and 7 ulcers improved significantly (79.4% average ulcer size decrease) after 10 weeks in real LEPT treatment group, in placebo LEPT group, only 31.9% of total ulcer area decrease was observed; none of the ulcers healed completely.</p>	<p>No SS difference</p> <p><u>Note:</u> 42 pts. Were treated with real vs. placebo LLLT (for 12 weeks)³.</p> <p>No SS difference</p> <p><u>Note:</u> 12 chronic leg ulcers were treated with real vs. placebo LLLT, total of 20 treatments⁴.</p>	

Legend:

LLLT - low energy laser therapy; LEPT - low energy photon therapy; CT - conventional therapy; SGH - Scarborough General Hospital; EMH - Extra-Mural Hospital; SS - statistical significance; pts. - patients

References:

1. J. Telfer, Trial on Laser Therapy for leg ulcers. Scarborough General Hospital MedNews, Vol. 6, No. 2, p. 17, 1993.
2. T. Lundberg, and M. Malm, Low-power HeNe Laser Treatment of Venous Leg Ulcers, Annals of Plastic Surgery, Vol. 27, No. 6, pp. 337-9, 1991.
3. M. Malm, and T. Lundberg, Effect of Low-Power Gallium-Arsenide Laser on Healing of Venous Ulcers, Scand. J. Plast. Reconstr. Surg., Vol. 25, pp. 249-251, 1991.
4. P.P. Gogia and R.R. Marquez, Effects of HeNe Laser on Wound Healing, Ostomy/Wound Management, Vol. 38, No. 6, p. 38-41, 1992.

Table 12
Comparative analysis of LEPT/LLLT/conventional therapy efficacy for carpal tunnel syndrome

Condition	Efficacy of CTS healing		
	LEPT	LLLT	Conventional Therapy
Carpal tunnel syndrome (CTS)	<p>15 patients free of symptoms & returned to work (71.4%)</p> <p>2 reduction of symptoms (9.5%)</p> <p>These patients remained free of symptoms after 6-18 months follow-up.</p> <p><u>Note:</u></p> <p>21 patients with CTS received LEPT (3 x week, 15 Rx total).</p>	<p>76.1% (by 60-80% limited) pain reduction only</p> <p>Only 36.5% had limited (by 60-80%) pain reduction after 6 months¹.</p> <p>62% return to work</p> <p><u>note:</u></p> <p>160 pts. were given 8 points conservative treatment program plus real or placebo LLLT (3 x week, 15 Rx total). The difference in terms of return to work was statistically significant (62% vs. 38%) in real vs. placebo LLLT. There were no mention of follow-up².</p>	<p>11-40% of patients remained free of symptoms in 6-18 months follow-up after the course of therapy.</p> <p><u>Note:</u></p> <p>wrist immobilization with splint, nonsteroid anti-inflammatory drugs, corticosteroid injections into the carpal tunnel^{3,4,5}</p>

Legend:

LLLT - low energy laser therapy; LEPT - low energy photon therapy; CTS - carpal tunnel syndrome; CT - conventional therapy; pts. - patients

References:

1. R. Storaci, F. Prato, La Laser-terapia Nella Sindrome del Tunnel Carpale, Laser & Technology, Vol. 3, No. 1-2, pp. 36-39, 1993.
2. F. Chadwick, C. Smith, T. Vangsness, T. Anderson, W. Good, Treatment of Repetitive Use Carpal Tunnel Syndrome, An International Symposium on Biomedical Optics, 4-10 Feb., San Jose, USA, Technical Abstracts, p. 194.
3. Goodman, H.V., Foster J.B., Effect of local corticosteroid injection on median nerve conduction in carpal tunnel syndrome, Ann. Phys. Med., Vol. 6, pp. 287, 1962 (ref. 16 from R. Szabo).
4. Gelberman R.H., Aronson D., Weisman M.H., Carpal tunnel syndrome: Results of a prospective trial of steroid injection and splinting, J. Bone Joint Surg., Vol. 62A, p. 1181, 1980, (ref. 15 from R. Szabo).
5. S.J. Kaplan, S.Z. Glicke, and R.G. Eaton, Predictive Factors in the Nonsurgical Treatment of Carpal Tunnel Syndrome, J. Of Hand Surgery, (British Volume, 1990), Vo. 15B, pp. 106-108.

Table 13
Comparative analysis of LEPT Manipulative Therapy/Exercise program efficacy for acute whiplash injury

Condition	Efficacy of LEPT in combined therapy for whiplash injury*		
	MT + Ex + LEPT	MT + Ex	MT
Acute whiplash injury	EMS (neck extensor muscle strength) 23% improvement ss p<0.05	EMS 15% improvement	EMS 9% improvement
	US (uninterrupted sleep) 37% improvement ss p <0.01	US 22% improvement	US 10% improvement

ss - statistically significant
*54 patients with acute whiplash injury were randomly assigned to the following 3 groups:
- 17 patients received manipulation therapy (MT)
- 18 patients received MT plus exercises (Ex)
- 19 patients received MT+Ex+Low Energy Photon Therapy (LEPT)
Therapy was administered 3 x week for 8 weeks.

Table 14

Clinical Entity	# of Cases	SI	I	MI	No Effect
Osteoarthritis	54	15 (28%)	22 (41%)	9 (16%)	8 (15%)
Soft tissue pathological conditions	69	24 (35%)	23 (33%)	16 (23%)	6 (9%)
Degenerative disc disease	62	20 (32%)	17 (27%)	14 (23%)	11 (18%)
Neuromuscular conditions	14	3 (21%)	5 (36%)	4 (29%)	2 (14%)
Total	199	62 (31%)	67 (34%)	43 (22%)	27 (13%)

Legend:

SI - significant improvement

I - improvement

MI - marginal improvement

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While preferred embodiments of the invention have been described, it will be appreciated that various changes may be made within the scope and spirit of the invention.

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WE CLAIM:

1. An apparatus for treating a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters, comprising:
 - 5 (a) a power source for providing power to a central microprocessor;
 - (b) a central microprocessor having stored optical parameter protocols suitable for treating a range of disorders of biological tissue and means for selecting one or more stored optical parameter protocols for the disorder to be treated;
 - 10 (c) at least one optical probe, having a microprocessor in communication with the central microprocessor, to receive the selected optical parameter protocol, said probe containing an optical source for generating a beam of light having the selected optical parameter protocol and for directing the beam of light to the biological tissue to be treated ; and
 - 15 (d) communication means for transmitting the optical parameter protocol from the central microprocessor to the heads.
 - 20
2. The apparatus of claim 1 wherein the beam of light having the selected optical parameter protocol is substantially monochromatic and has a wavelength of from 400 to 2,000 nm.
- 25 3 The apparatus of claim 2 wherein the beam of light has a wavelength in the range of from 630 to 700 nm, from 740 to 760 nm, or from 800 to 1,100 nm.
4. The apparatus of claim 1 wherein the optical source is a laser,

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laser diode, light emitting or superluminous diode, which provides substantially monochromatic light.

5 5. The apparatus of claim 4 including means for operating the optical source in pulsed mode with a pulse repetition rate in a range of from 0 to 200 Hz.

10 6. The apparatus of claim 1 wherein the optical parameters are selected from the group comprising dose, intensity, frequency, pulse duration, wavelength, power, monochromaticity, intensity modulation with specific endogenous frequencies, three-dimensional photon distribution.

7. The apparatus of claim 1 wherein the communication means are wireless.

15 8. The apparatus of claim 7 including a plurality of probes for each central microprocessor, each probe being capable, independently of the remaining probes, of receiving one or more optical parameter protocols from said central microprocessor.

9. The apparatus of claim 1, 7 or 8 wherein said communication means includes a telephone link.

20 10. The apparatus of claim 1 further comprising means for monitoring the condition of the mammal and providing feedback to the central microprocessor to adjust the selected optical parameter protocol including adjustment of the phase of stimulation in respect to the endogenous rhythm phase based on the condition of the mammal.

11. The apparatus of claim 8 wherein the means for monitoring the

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condition of the mammal is on-line EEG, EMG, ECG, or a respirator.

12. The apparatus of claim 1 wherein said probe includes a matrix of optical sources arranged in a square or rectangular pattern, to provide three dimensional photon distribution in the affected area.

5 13. The apparatus of claim 1 wherein said probe includes a matrix of optical sources arranged in a circular pattern.

14. The apparatus of claim 13 wherein said circular pattern provides photons in an area $(R+1)^2/R^2$, where R is the radius of an affected area of said biological tissue.

10 15. The apparatus of claim 1 wherein said optical probe includes two sets of optical sources, one set comprising a single light source arranged on a stalk, and the other comprising a matrix of optical sources arranged on a face of said optical head.

15 16. The apparatus of claim 1 wherein said optical probe includes a flexible body capable of adapting to the contours of a portion of a patient to be treated, and a plurality of said optical sources arranged on said flexible body.

20 17. The apparatus of claim 1 wherein said optical probe includes a body arranged in a circular configuration and adapted to fit on the finger of a patient, said body having an inner surface, and at least one optical source arranged on said inner surface.

18. An apparatus for treating dermatological, musculoskeletal, soft tissue or neurological disorders of a biological tissue with non-ionizing low energy light having selected optical parameters, comprising:

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- (a) a power source for providing power to a central microprocessor;
- (b) a central microprocessor having stored optical parameter protocols suitable for treating a range of said disorders of biological tissue and means for selecting one or more stored optical parameter protocols for the disorder to be treated, said parameters including wavelength, power, intensity and dose;
- (c) an optical probe, having a microprocessor in communication with the central microprocessor, to receive the selected optical parameter protocol, said probe containing an optical parameter protocol said probe containing an optical source for generating a beam of light having the selected optical parameter protocol and for directing the beam of light to the biological tissue to be treated;
- (d) said optical source including an array of light emitting sources, all of said sources when activated producing substantially monochromatic non-ionizing light having a selected wavelength in the range of from 630 to 2000 nm and a bandwidth not exceeding substantially 30 to 40 nm, and each of said sources providing light of the same said selected wavelength and no other wavelength;
- (e) said optical source further including a control circuit for activating selected ones of said light emitting sources to produce a three dimensional light distribution of said tissue;
- (f) said protocols including a protocol for providing said beam of light as said substantially monochromatic non-ionizing light to stimulate said tissue;
- (g) communication means for transmitting the optical parameter protocol from the central microprocessor to said

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at least one probe; and

(h) said probe containing said protocol only for said selected wavelength and not containing any protocol for any other wavelength.

5 19. The apparatus of claim 18 wherein the beam of light has a wavelength in the range of from 630 to 700 nm, from 740 to 760 nm, or from 800 to 1,100 nm.

10 20. The apparatus of claim 18 wherein the optical source is a laser, laser diode, light emitting or superluminous diode, which provides substantially monochromatic light.

21. The apparatus of claim 20 including means for operating the optical source in pulsed mode with a pulse repetition rate in a range of from 0 to 200 Hz.

15 22. The apparatus of claim 18 wherein the optical parameters are selected from the group comprising dose, intensity, frequency, pulse duration, wavelength, power, monochromaticity, intensity modulation with specific endogenous frequencies, three-dimensional photon distribution.

20 23. The apparatus of claim 18 wherein the communication means are wireless.

24. The apparatus of claim 23 including a plurality of probes for each central microprocessor, each probe being capable, independently of the remaining probes, of receiving one or more optical parameter protocols from said central microprocessor.

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25. The apparatus of claim 18, 23, or 24 wherein said communication means includes a telephone link between said central microprocessor and said at least one probe, and a communication interface between said telephone link and said at least one probe, said
5 telephone link including a modem, so that said at least one probe may receive said optical parameter protocol remotely over said telephone link.

26. The apparatus of claim 18 further comprising means for monitoring the condition of the mammal and providing feedback to the
10 central microprocessor to adjust the selected optical parameter protocol including adjustment of the phase of stimulation in respect to the endogenous rhythm phase based on the condition of the mammal.

27. The apparatus of claim 26 wherein the means for monitoring the condition of the mammal is on-line EEG, EMG, ECG, a respirator, or
15 chemoluminescence.

28. The apparatus of claim 18 wherein said light emitting sources are arranged in a square or rectangular pattern, to provide said three dimensional photon distribution in the affected area.

29. The apparatus of claim 18 wherein said light emitting sources
20 are arranged in a circular pattern.

30. The apparatus of claim 29 wherein said circular pattern provides photons in an area $(R+1)^2/R^2$, where R is the radius of an affected area of said biological tissue.

31. The apparatus of claim 18 wherein said optical probe includes
25 two sets of light emitting sources, one set comprising a single light source

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arranged on a stalk, and the other comprising a matrix of light emitting sources arranged on a face of said optical probe.

32. The apparatus of claim 18 wherein said light emitting probe includes a flexible body capable of adapting to the contours of a portion of
5 a patient to be treated, and a plurality of said optical sources arranged on said flexible body.

33. The apparatus of claim 18 wherein said optical probe includes a body arranged in a circular configuration and adapted to fit on the finger
10 of a patient, said body having an inner surface, and a plurality of light emitting sources arranged on said inner surface.

34. The apparatus of claim 18 wherein said probe contains an optical parameter protocol such that said probe provides a dose
15 of from 0.05 to 10 J/cm², an intensity of from 0.2 to 100 mW/cm², a wavelength of from 630 to 2,000 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz and 1 to 5 Hz.

35. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose
20 of from 0.05 to 0.2 J/cm², a wavelength of from 630 to 700 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

36. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose
25 of from 2.0 to 5.0 J/cm², a wavelength of from 630 to 700 nm, a continuous wave

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mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

37. The apparatus of claim 18 wherein said probe contains an optical parameter protocol such that said probe provides a dose of from 3.0 to 9.0 J/cm², an intensity of from 50.0 to 80 mW/cm² and a wavelength of from 630 to 700 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, to 1.2 Hz, and 1 to 5 Hz.

38. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose of from 0.1 to 9.0 J/cm², an intensity o from 300 to 600 mW/cm² and a wavelength of from 800 to 1,100 nm in a continuous wave (CW) mode or pulse repetition rate of 10 Hz or from 50 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of 0.3 and/or 1.2 Hz.

39. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose of from 2 to 5 J/cm², an intensity of from 10 to 30 mW/cm² and a wavelength of from 630 to 700 nm.

40. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose of from 3 to 7 J/cm² or 4 to 25 J/cm², an intensity of from 10 to 40 mW/cm² to 60 to 100 mW/cm² or 300-600 mW/cm² or 1000 to 5000 mW/cm² and a wavelength of from 800 to 1100 nm.

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41. The apparatus of claim 34 wherein said probe contains an optical parameter protocol such that said probe provides a dose of from 4 to 9 J/cm², an intensity of from 20 to 60 mW/cm² and a wavelength of from 630 to 700 nm.

5 42. The apparatus of claim 18 wherein said control circuit includes a circuit for activating said light emitting sources with a selected pulse repetition rate.

43. The apparatus of claim 18 wherein said optical parameter protocol in said probe is selected according to the color of skin of the
10 patient to be treated.

44. A method for programming apparatus for treating a disorder of biological tissue by stimulating the biological tissue with light having selected optical parameters, comprising:

- 15 (a) storing in a central memory a plurality of optical parameter protocols suitable for treating a range of disorders of biological tissue,
- (b) providing a probe unit containing at least one optical source for generating a beam of light,
- 20 (c) and transferring to said probe unit from the central memory at least one desired optical parameter protocol,
- so that said probe unit may on operation apply the desired optical parameter protocol to the tissue to be treated.

45. A method according to claim 44 and including the step of transferring said optical parameter protocol from said central memory to
25 said probe unit by wireless.

46. A method according to claim 44 and including the step of

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transferring said optical parameter protocol from said central memory to said probe unit by telephone link.

47. A method according to claim 44 and including the step of transferring different optical parameter protocols to a plurality of probe units from a common central memory.

48. A method according to claim 47 wherein, after each probe unit has received said at least one optical parameter protocol from said central memory, such probe unit is removed to a location remote from such central memory, for use.

49. A method according to claim 48 wherein said location is a patient's home.

50. A method for stimulating healing of a disorder of a biological tissue in a mammal by stimulating the biological tissue with light having selected optical parameters, comprising:

- (a) providing a central microprocessor having stored optical parameter protocols suitable for treating a range of disorders of biological tissue;
- (b) selecting one or more stored optical parameter protocols for the disorder to be treated;
- (c) generating a beam of light having the selected optical parameter protocol and directing the beam of light to the biological tissue to be treated.

51. A method of stimulating healing of a lesion in a mammal, comprising: irradiating the lesion with a substantially monochromatic beam of light having predetermined optical parameters, wherein the predetermined optical parameters include a dose of from 0.05 to 10 J/cm²,

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an intensity of from 0.2 to 100 mW/cm², a wavelength of from 400 to 2,000 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

52. The method of claim 51 wherein the lesion is an ulcer or a wound and the selected optical parameters include a dose of from 0.05 to 0.2 J/cm², a wavelength of from 600 to 700 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

53. The method of claim 51 wherein the lesion is an ulcer or wound in acute inflammatory condition and the selected optical parameters include a dose of from 2.0 to 5.0 J/cm², an intensity of from 10.0 to 30 mW/cm², and a wavelength of from 600 to 700 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

54. The method of claim 51 wherein the lesion is an infected wound and the selected optical parameters include a dose of from 3.0 to 9.0 J/cm², an intensity of from 50.0 to 80 mW/cm² and a wavelength of from 600 to 700 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, to 1.2 Hz, and 1 to 5 Hz.

55. The method of claim 51 wherein the lesion is an ulcer or a

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wound in the area with impaired microcirculation and the selected optical parameters include a dose of from 0.1 to 9.0 J/cm², an intensity of from 300 to 600 mW/cm² and a wavelength of from 800 to 1,100 nm in a continuous wave (CW) mode or with pulse repetition rate of 10 Hz or
5 from 50 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of 0.3 and/or 1.2 Hz and the area to be treated is the skin surrounding the lesion.

56. The method of claim 51 where the lesion is an ulcer or wound
10 and the selected optical parameters include a suitable combination of the optical parameters of claims 52, 53, 54 and 55 depending on the ulcer or wound condition or stage.

57. The method of claim 51 wherein the lesion is a post-surgical scar in an acute inflammatory condition and the selected optical
15 parameters include a dose of from 2 to 5 J/cm², an intensity of from 10 to 30 mW/cm² and a wavelength of from 600 to 700 nm.

58. The method of claim 51 wherein the lesion is a post-surgical scar in a sub-acute inflammatory condition and the selected optical
20 parameters include a dose of from 3 to 7 J/cm² or 4 to 25 J/cm², an intensity of from 10 to 40 mW/cm² or 60 to 100 mW/cm² or 300-600 mW/cm² or 1000 to 5000 mW/cm² and a wavelength of from 800 to 1100 nm.

59. The method of claim 51 wherein the lesion is induced by Herpes Simplex virus (cold sore) or acne and the selected optical parameters
25 include a dose of from 4 to 9 J/cm², an intensity of from 20 to 60 mW/cm² and a wavelength of from 630 to 700 nm.

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60. A method of stimulating healing of acute and chronic musculo-skeletal and neuromuscular pathological conditions in soft tissue (muscle, tendons, ligaments, nerves, etc.), bones and joints in a mammal, comprising: irradiating the affected area with a substantially
5 monochromatic beam of light having predetermining optical parameters, wherein the predetermined optical parameters include a dose of from 0.1 to 150 J/cm², an intensity of from 1 to 10000 mW/cm², a wavelength of from 400 to 2000 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, or from 1000 to 10000 Hz, optional
10 modulation frequencies of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz, and selected phases of stimulation in respect to the phase of endogenous rhythm of from 0 to 90°.

61. A method of stimulating healing of post-traumatic conditions in soft tissue (skin, muscles, tendons, ligaments, nerves, etc.), bones and
15 joints in a mammal comprising: irradiating the traumatized area or selected points in the affected area with a substantially monochromatic beam of light having predetermined optical parameters wherein the predetermined optical parameters include a dose of from 3 to 100 J/cm², an intensity of from 1 to 5000 mW/cm² and a wavelength of from 400 to
20 2000 nm, and a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz.

62. The methods of claim 60 or 61 wherein the condition to be treated is in the acute stage of inflammatory condition and the selected optical parameters include doses of from 3 to 10 J/cm², intensities of from
25 10 to 40 mW/cm² and 30 to 100 mW/cm² and wavelengths of from 630 to 700 nm and 800 to 1100 nm, and a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz.

63. The method of claim 60 or 61 wherein the condition to be

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5 treated is accompanied by hematoma, bruise and the selected optical parameters for hematoma, bruise healing acceleration include doses of from 5 to 14 J/cm², intensities of from 20 to 50 J/cm², a wavelength of from 630 to 700 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz and 1 to 5 Hz.

10 64. The method of claim 60 or 61 wherein the condition to be treated is in the sub-acute stage of inflammatory condition and the selected optical parameters include doses of from 3 to 7 J/cm² and 4 to 25 J/cm², intensities of from 10 to 40 mW/cm² and 60 to 100 mW/cm² and 300 to 600 mW/cm² and 1000 to 5000 mW/cm² and a wavelength of from 800 to 1100 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz.

15 65. The method of claim 60 or 61 wherein the condition to be treated is in the stage of regeneration of tissue, normalization of function and the selected optical parameters include doses of from 3 to 5 J/cm² and 4 to 25 J/cm², intensities of from 60 to 100 mW/cm² and 300 to 600 mW/cm² and 1000 to 5000 mW/cm² and a wavelength of from 800 to 1100 nm, and a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz.

25 66. The method of stimulating healing of a chronic inflammation in soft tissue and/or joints in a flare-up stage of pre-existing musculo-skeletal or neuromuscular pathological conditions (e.g. tendinitis, bursitis, epicondylitis, arthritis, rheumatoid arthritis, ankylosing spondylitis, repetitive strain injuries, etc.) in a mammal comprising:

(a) irradiating the affected area with a substantially monochromatic beam of light having predetermined optical

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parameters wherein the predetermined optical parameters include a dose of from 0.1 to 0.5 J/cm², an intensity of from 1 to 10 mW/cm², a wavelength of from 630 to 700 nm or 800 to 1100 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz.

5

(b) and in addition, irradiating selected points or areas on the body with a substantially monochromatic beam of light having predetermined optical parameters wherein the predetermined optical parameters include a dose of from 0.1 to 0.6 J/cm² and 1 to 5 J/cm², intensities of from 1 to 10 mW/cm², 10 to 30 mW/cm², 100 to 300 mW/cm², wavelengths of from 630 to 700 nm and 800 to 1100 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

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67. The method of stimulating healing of chronic inflammation in soft tissue and/or joint in a mammal with chronic musculo-skeletal or neuro-muscular conditions without flare-up (e.g. tendinitis, bursitis, epicondylitis, arthritis, rheumatoid arthritis, spurs, repetitive strain injuries, etc.) comprising: irradiating the affected area with a substantially monochromatic beam of light having predetermined optical parameters wherein the predetermined optical parameters include a dose of from 2 to 9 J/cm², 3 to 25 J/cm², 25 to 100 J/cm², intensities of from 5 to 30 mW/cm², 10 to 40 mW/cm², 60 to 100 mW/cm², 300 to 600 mW/cm², 1000 to 5000 mW/cm², a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz and 1 to 5 Hz.

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68. The method of stimulating healing of inflammatory degenerative joint diseases (arthritis, rheumatoid arthritis, degenerative disk disease, ankylosing spondylitis, repetitive strain injuries, etc.) in mammals, comprising: irradiating the affected area and/or selected points in the affected area with a substantially monochromatic beam of light having predetermined optical parameters wherein the predetermined optical parameters include doses of from 0.1 to 0.5 J/cm², 2 to 9 J/cm², 3 to 25 J/cm², 25 to 100 J/cm², intensities of from 1 to 10 mW/cm², 10 to 30 mW/cm², 60 to 100 mW/cm², 300 to 600 mW/cm² and 1000 to 5000 mW/cm², wavelengths of from 630 to 700 nm and 800 to 1100 nm, a continuous wave mode or pulse repetition rate of from 0 to 200 Hz, modulation frequencies of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz, and in addition, irradiating selected points or areas on the body with a substantially monochromatic beam of light having predetermined optical parameters, wherein the predetermined optical parameters include doses of from 0.1 to 0.5 J/cm², 1 to 5 J/cm², intensities of from 1 to 10 mW/cm² and 100 to 300 mW/cm², wavelengths of from 630 to 700 nm and 800 to 1100 nm, a continuous wave mode or a pulse repetition rate of from 0 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

69. The method of claim 60 wherein musculo-skeletal or neuromuscular pathological condition is accompanied by muscle spasm (myofascial pain, fibromyalgia, repetitive strain injuries or cumulative trauma disorders, sports injuries, etc.) and the selected optical parameters for muscle spasm relief include doses of from 0.1 to 0.5 J/cm², 3 to 5 J/cm², 4 to 25 J/cm² and 25 to 100 J/cm², intensities of from 1 to 10 mW/cm², 1 to 40 mW/cm², 60 to 100 mW/cm², 300 to 600 mW/cm² and 1000 to 10000 mW/cm², wavelengths of from 630 to 700 nm and 800 to 1100 nm, continuous wave mode or pulse repetition rates of from 0 to

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200 Hz and 1000 to 10000 Hz.

70. The method of claim 60 where musculo-skeletal or neuromuscular pathological conditions are accompanied by pain, tender and trigger points, (myofascial pain, fibromyalgia, repetitive strain injuries or cumulative trauma disorders, sports injuries, tendinitis, epicondylitis, bursitis, spurs, etc.) and the selected optical parameters for pain relief, tender and trigger point therapy include a dose of from 4 to 150 J/cm², intensities of from 60 to 100 mW/cm², 300 to 600 mW/cm², 800 to 10000 mW/cm², a wavelength of from 630 to 1100 nm, a continuous wave mode or a pulse repetition rate of from 50 to 200 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz and 1 to 5 Hz.

71. The method of claim 60 or 61 where the condition to be treated is accompanied by swelling, edema, and pain (e.g. post-traumatic, post-surgical complications, arthritis) and the selected optical parameters for swelling, edema and pain relief and lymphatic drainage activation include doses of from 5 to 14 J/cm², 25 to 100 J/cm², intensities of from 10 to 40 mW/cm², 300 to 600 mW/cm². And from 1000 to 5000 mW/cm², wavelengths of from 630 to 700 nm and 800 to 1100 nm, continuous wave mode or pulse repetition rates of from 0 to 200 Hz and 1000 to 10000 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

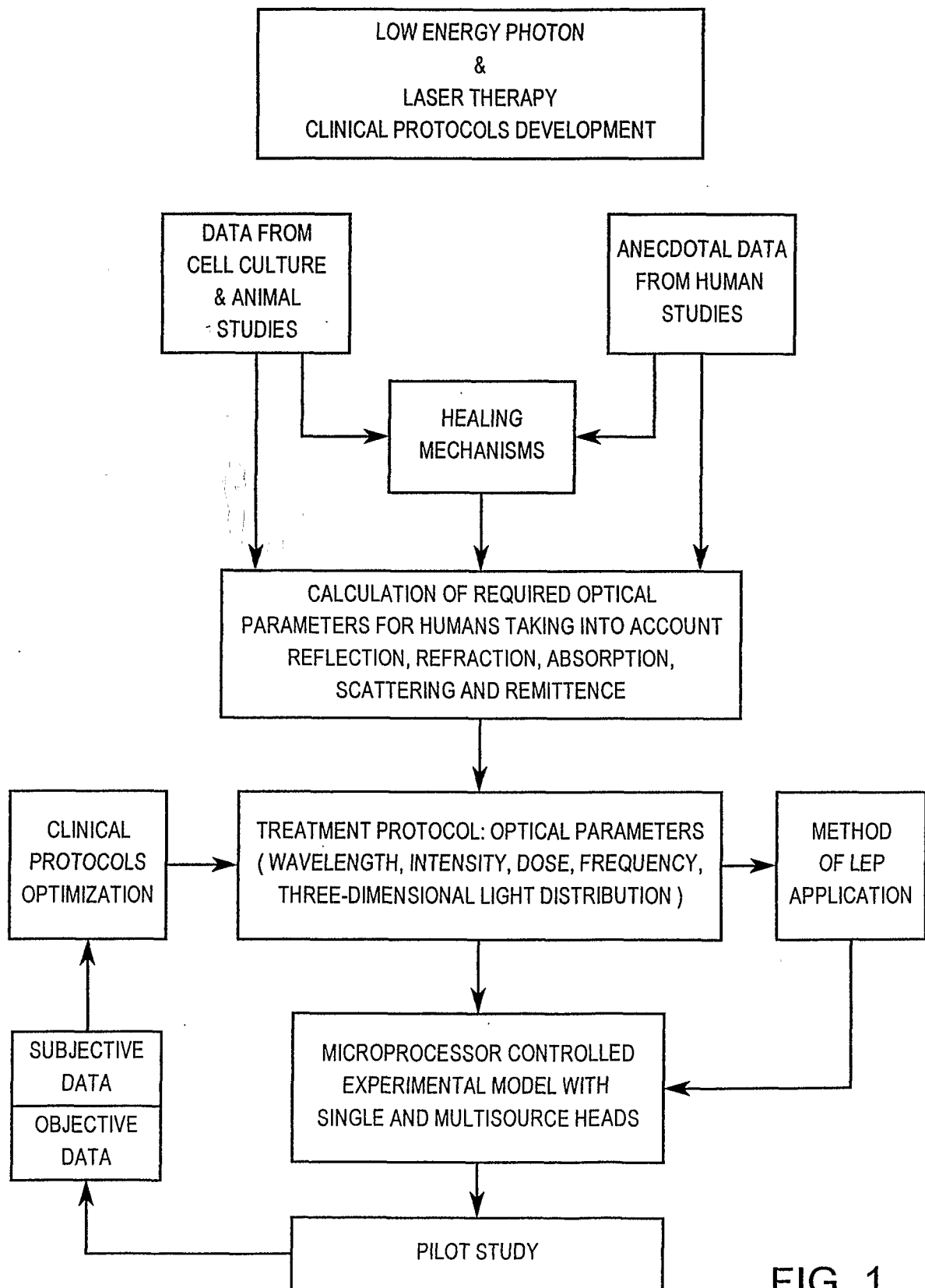
72. The method of claim 60 where said neuromuscular pathological condition is carpal tunnel syndrome and the selected optical parameters include doses of from 0.05 to 0.3 J/cm², 0.2 to 4.0 J/cm², 5 to 10 J/cm², and 25 to 150 J/cm², intensities of from 1 to 10 mW/cm², 60 to 100 mW/cm², 300 to 600 mW/cm², 1,000 to 10,000 mW/cm², continuous wave mode or

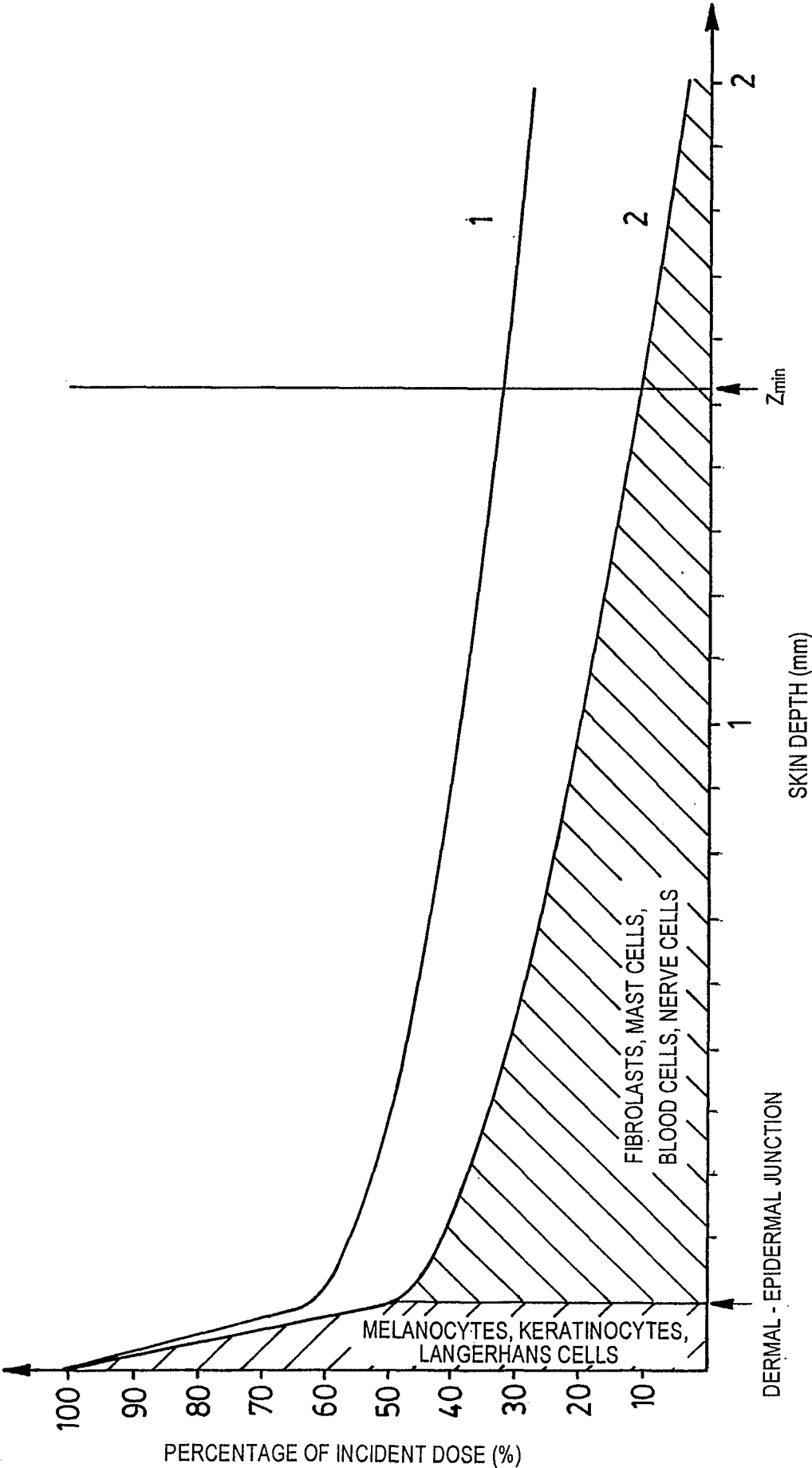
- 91 -

pulse repetition rates of from 0 to 200 Hz and 1000 to 10000 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz and 1 to 5 Hz.

- 5 73. The method of claim 60 where said neuromuscular pathological conditions are neuritis, neuralgia, trigeminal neuralgia and the selected optical parameters are doses of from 0.1 to 0.3 J/cm², 1 to 3 J/cm², 5 to 25 J/cm² and 25 to 80 J/cm², intensities are of from 1 to 10 mW/cm², 20 to 40 mW/cm², 100 to 400 mW/cm², 800 to 3000 mW/cm², continuous wave
10 mode or pulse repetition rates of from 0 to 200 Hz and 1000 to 10000 Hz, and optional modulation frequencies of said continuous wave mode or of said pulse repetition rate of any of from 0.2 to 0.3 Hz, 1 to 1.2 Hz, and 1 to 5 Hz.

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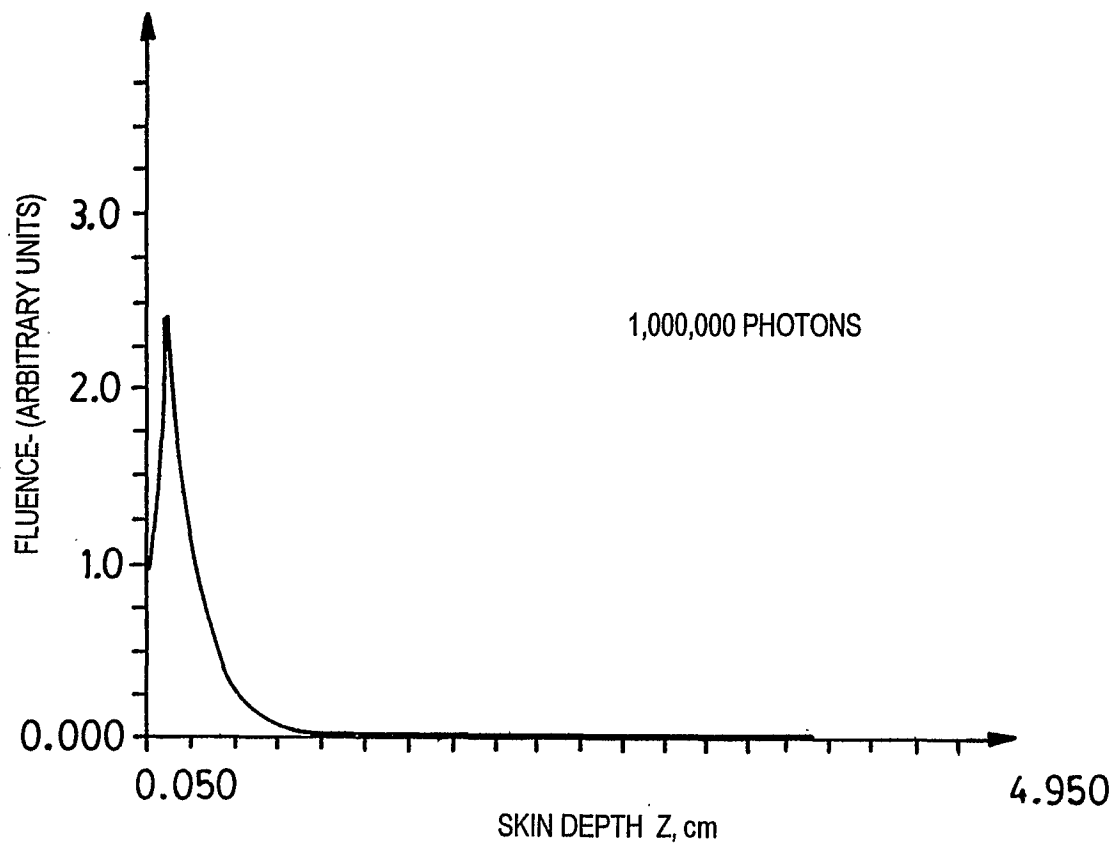
**FIG. 1**



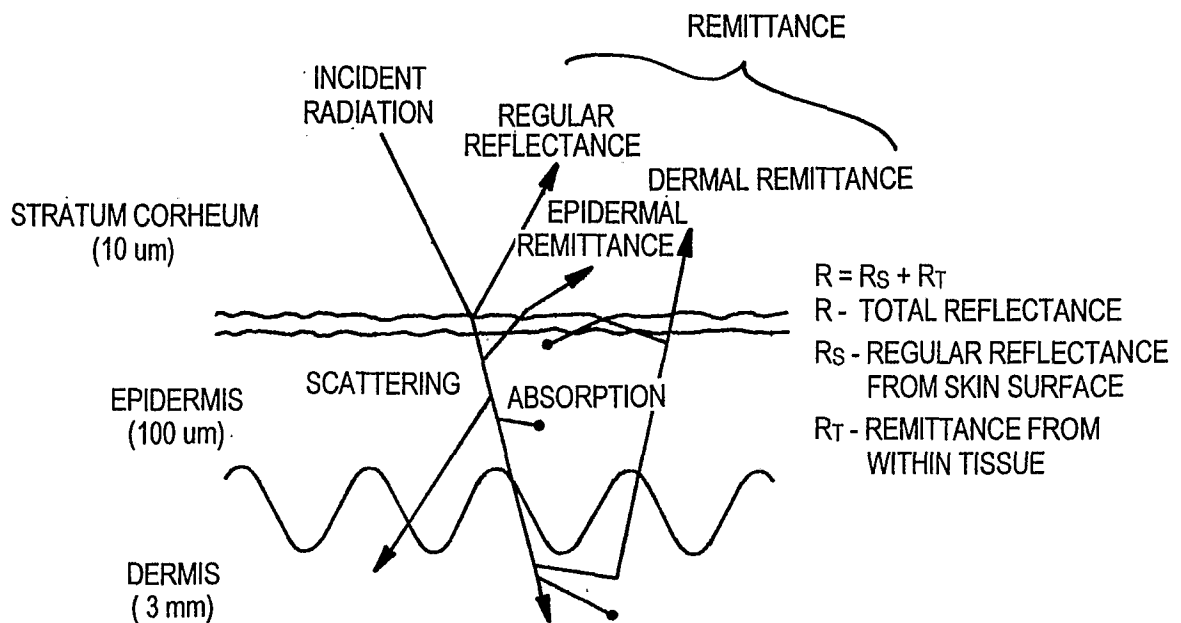
PERCENTAGE OF INCIDENT DOSE $(D/(1-R)D_0) \times 100\%$ RECEIVED BY
CELLS ON SKIN DEPTH Z. 1 - $\lambda = 630$ nm, 2 - $\lambda = 1,060$ nm.

FIG. 2

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RESULTS OF MONTE-CARLO SIMULATION OF
PHOTON PROPOGATION IN THE SKIN.
BEAM: FLAT, R = 1 cm.

FIG. 3**FIG. 4**

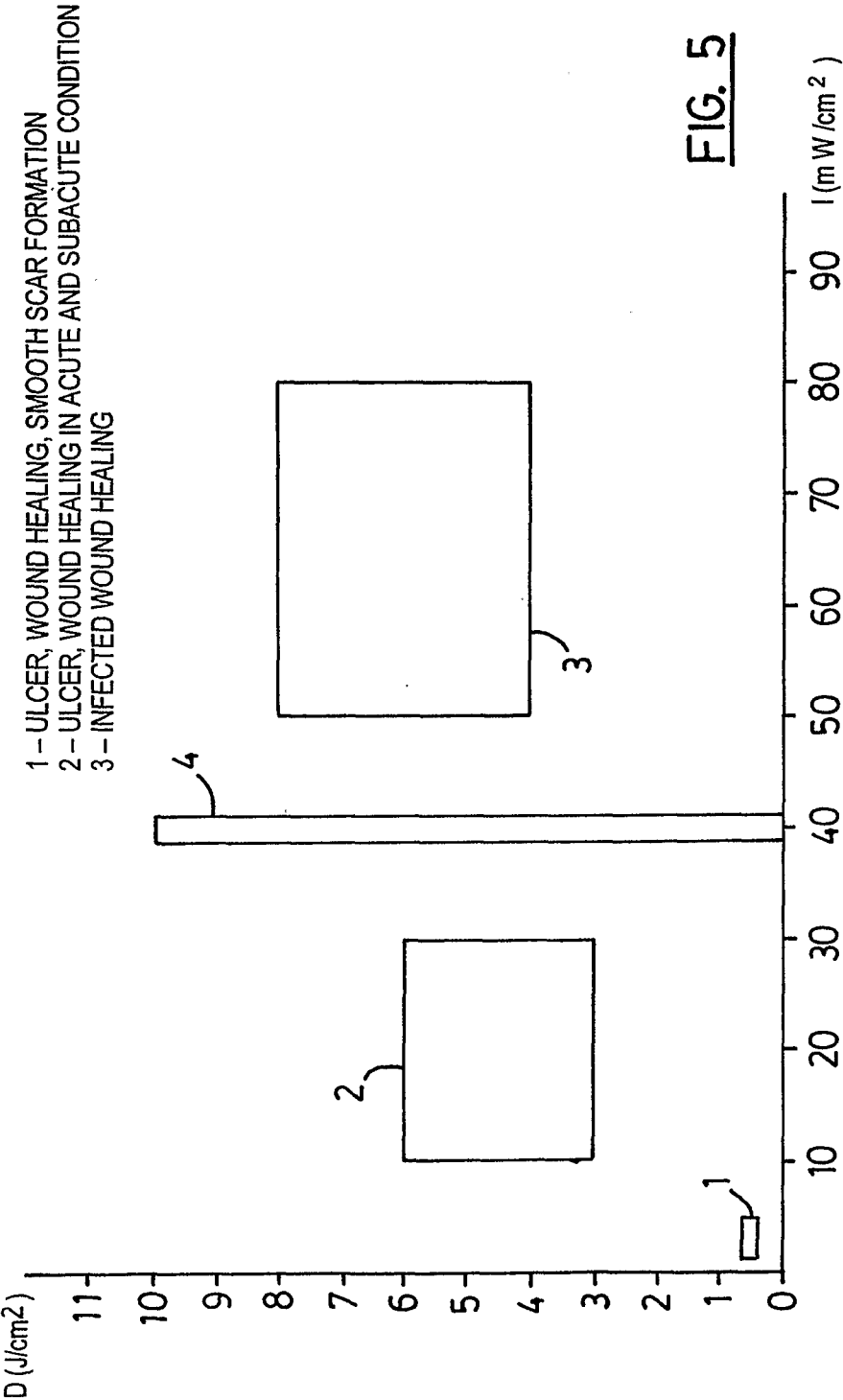


FIG. 5

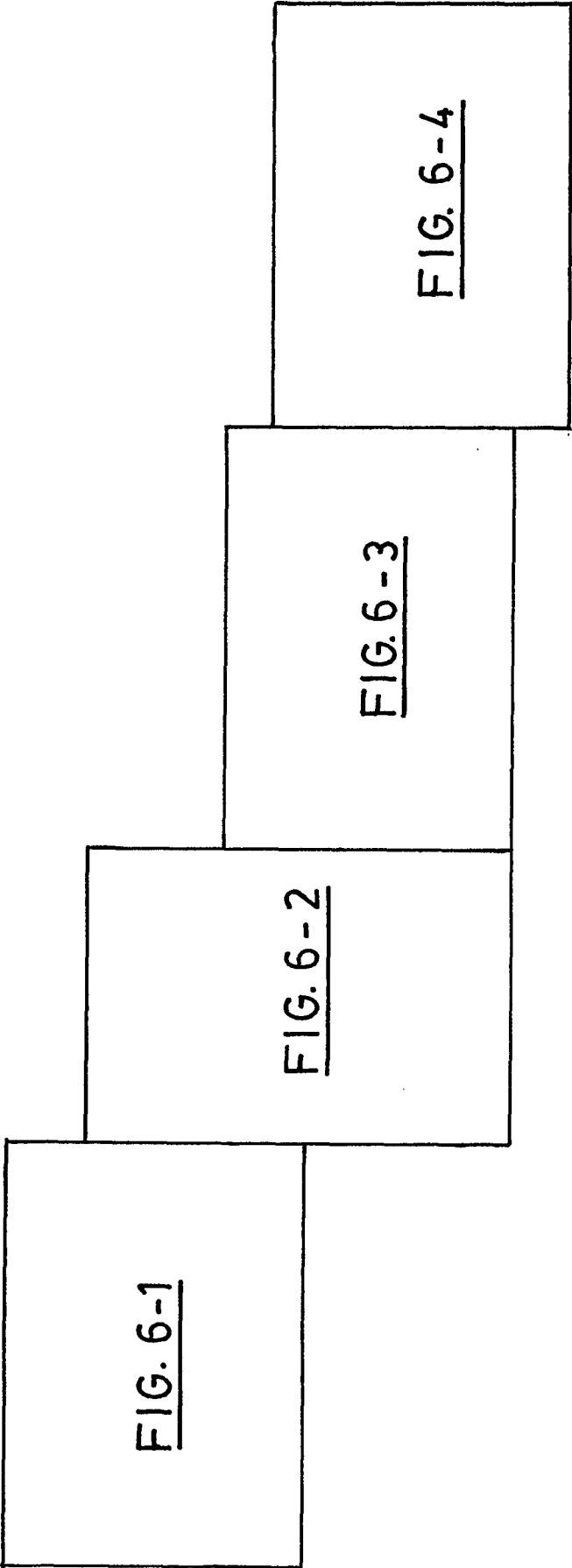


FIG. 6

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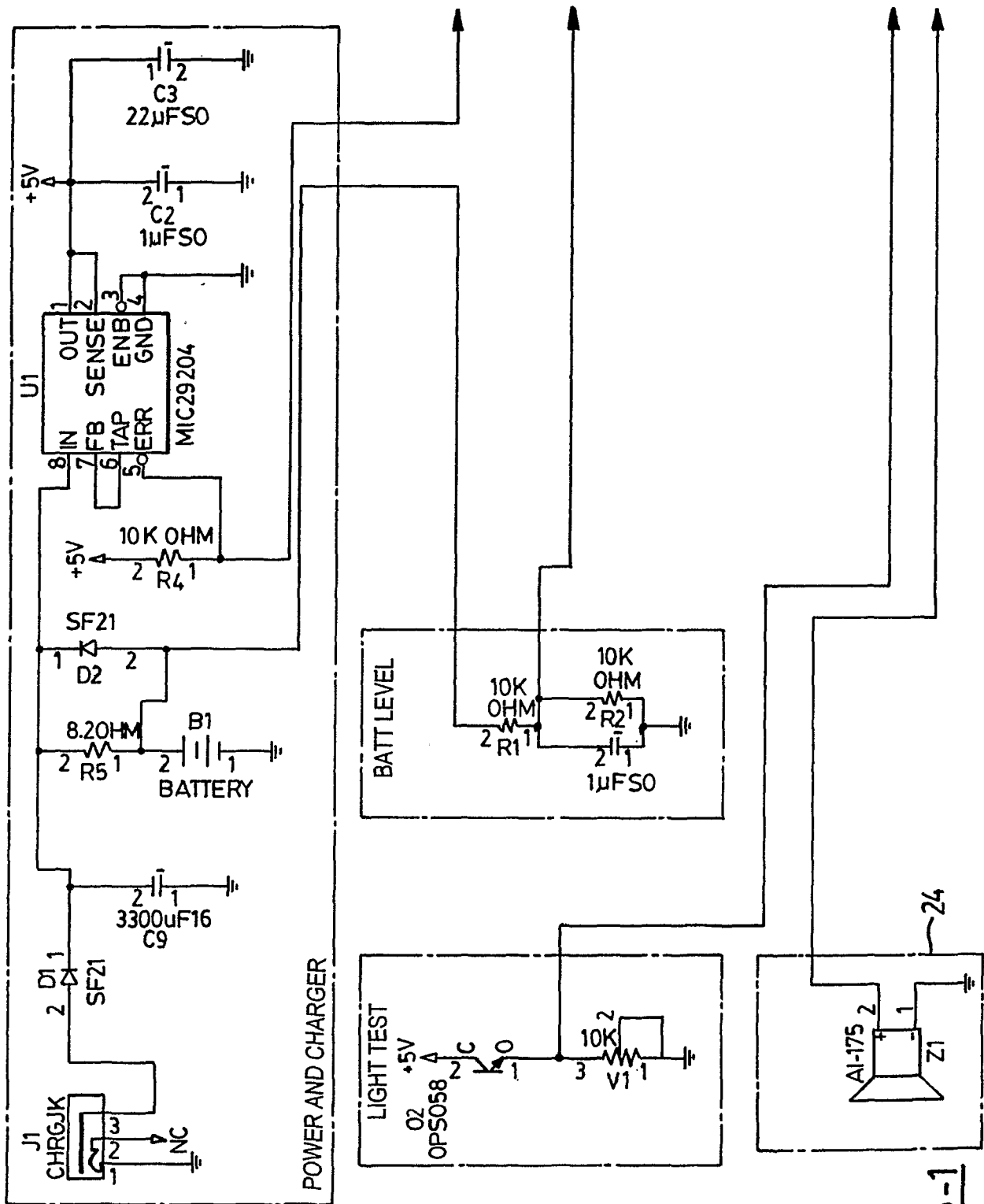
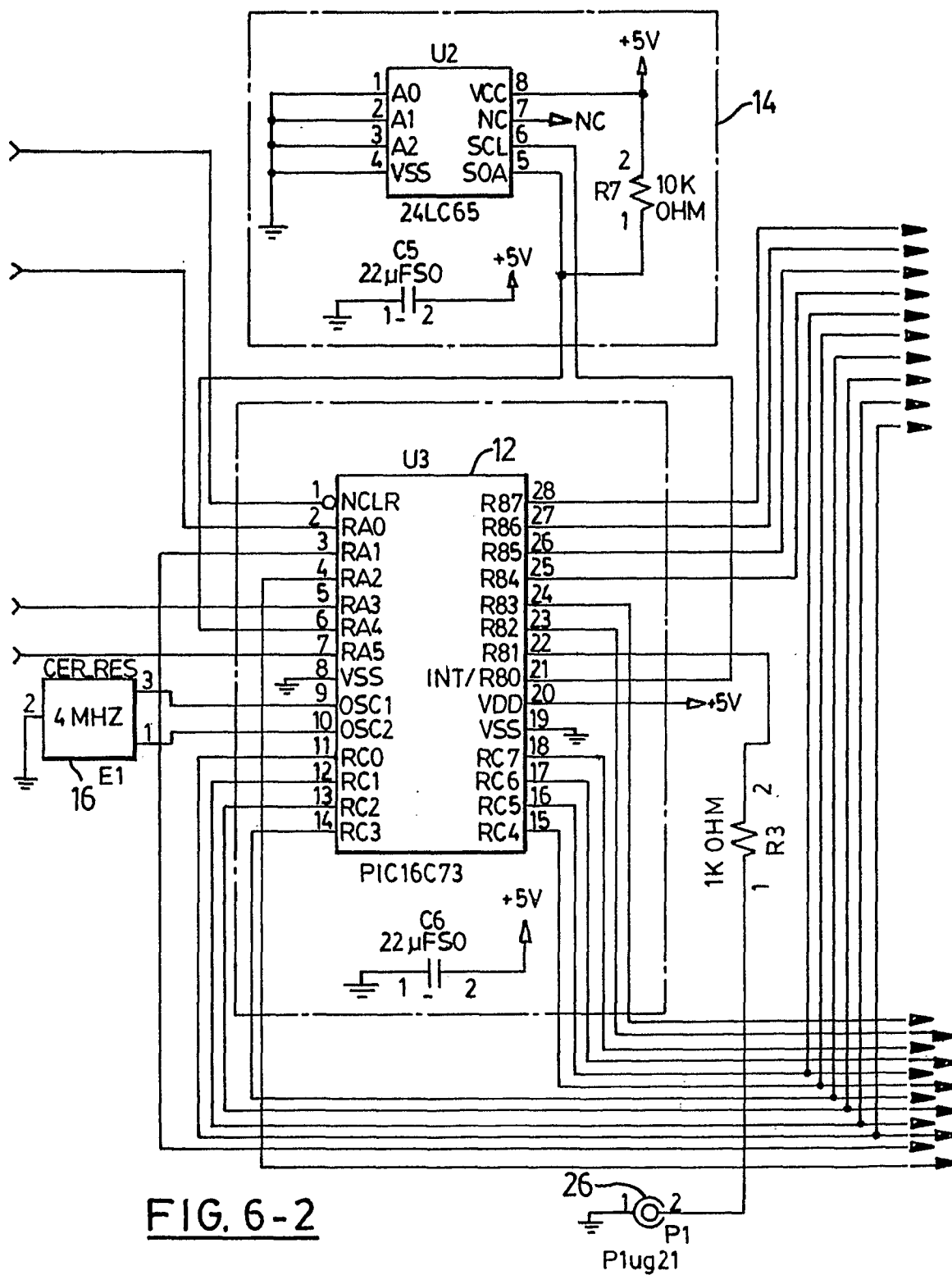


FIG 6-1



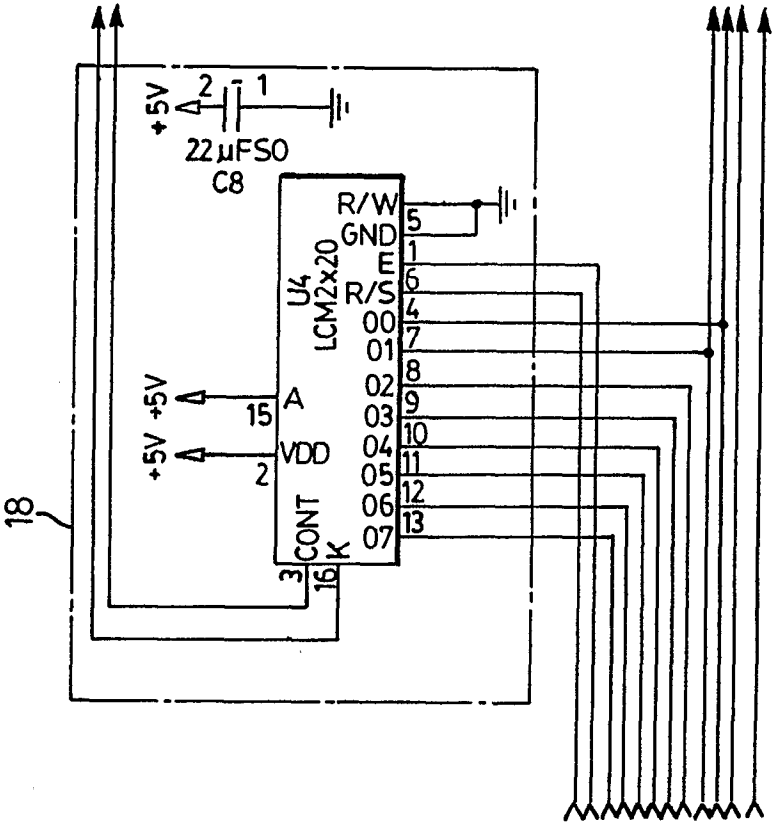
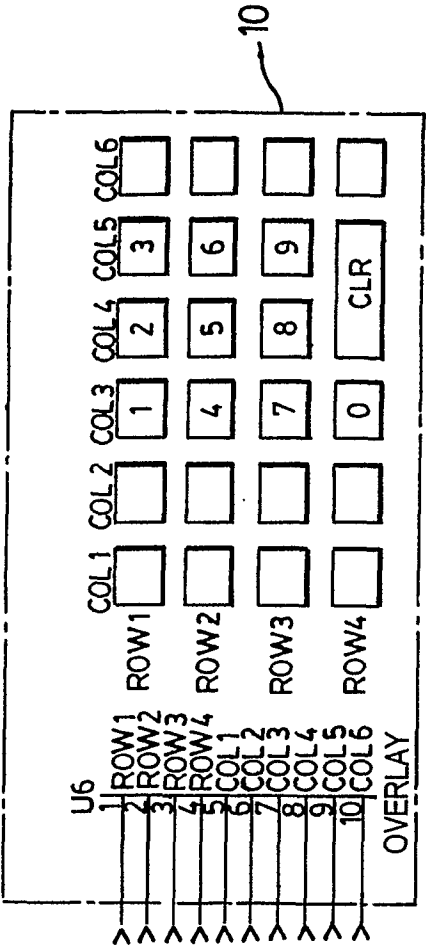


FIG. 6-3

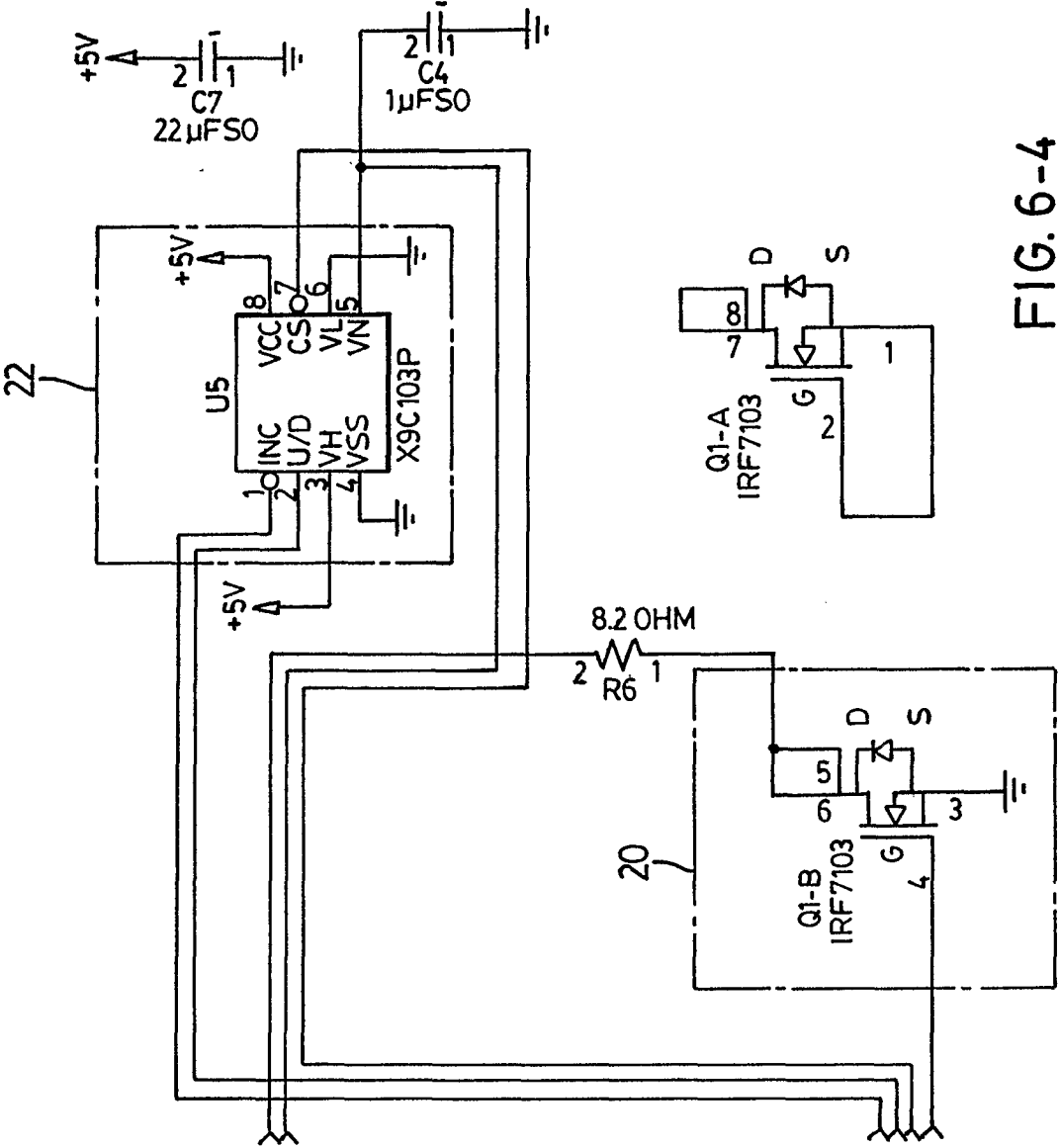


FIG. 6-4

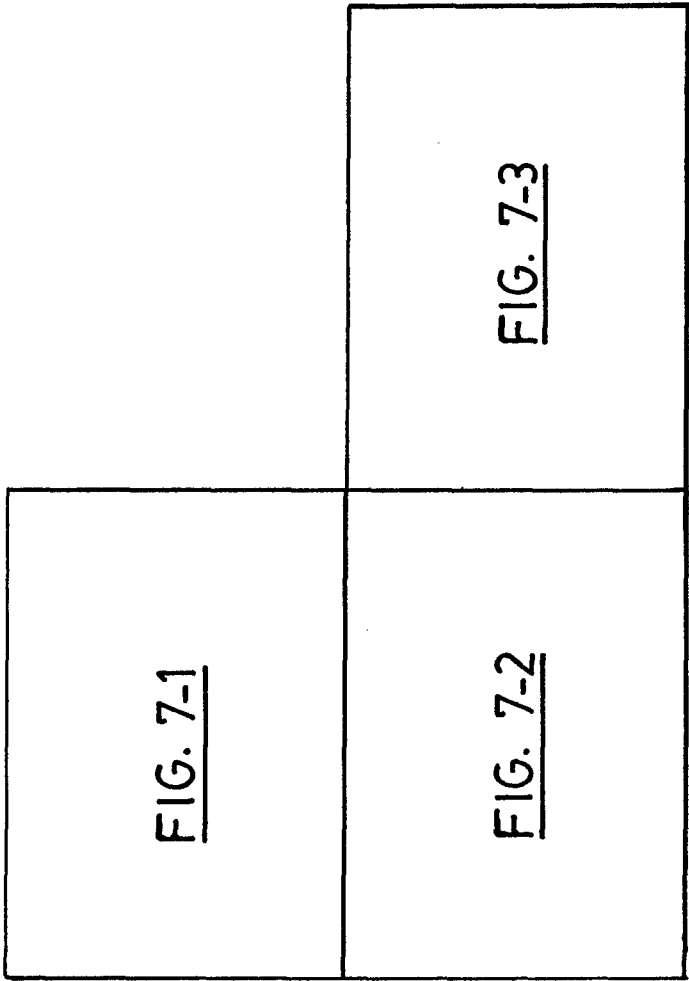


FIG. 7

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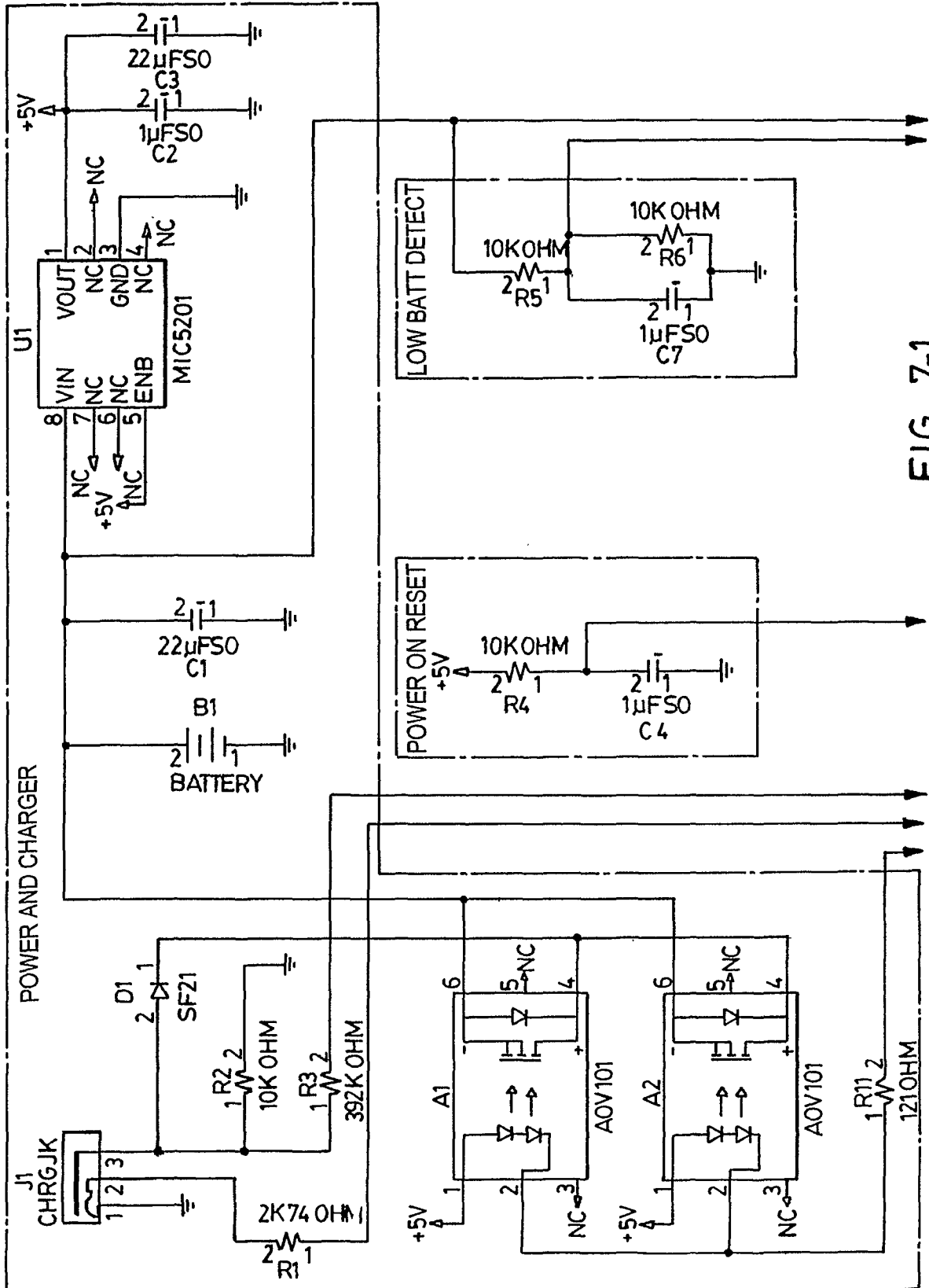


FIG. 7-1

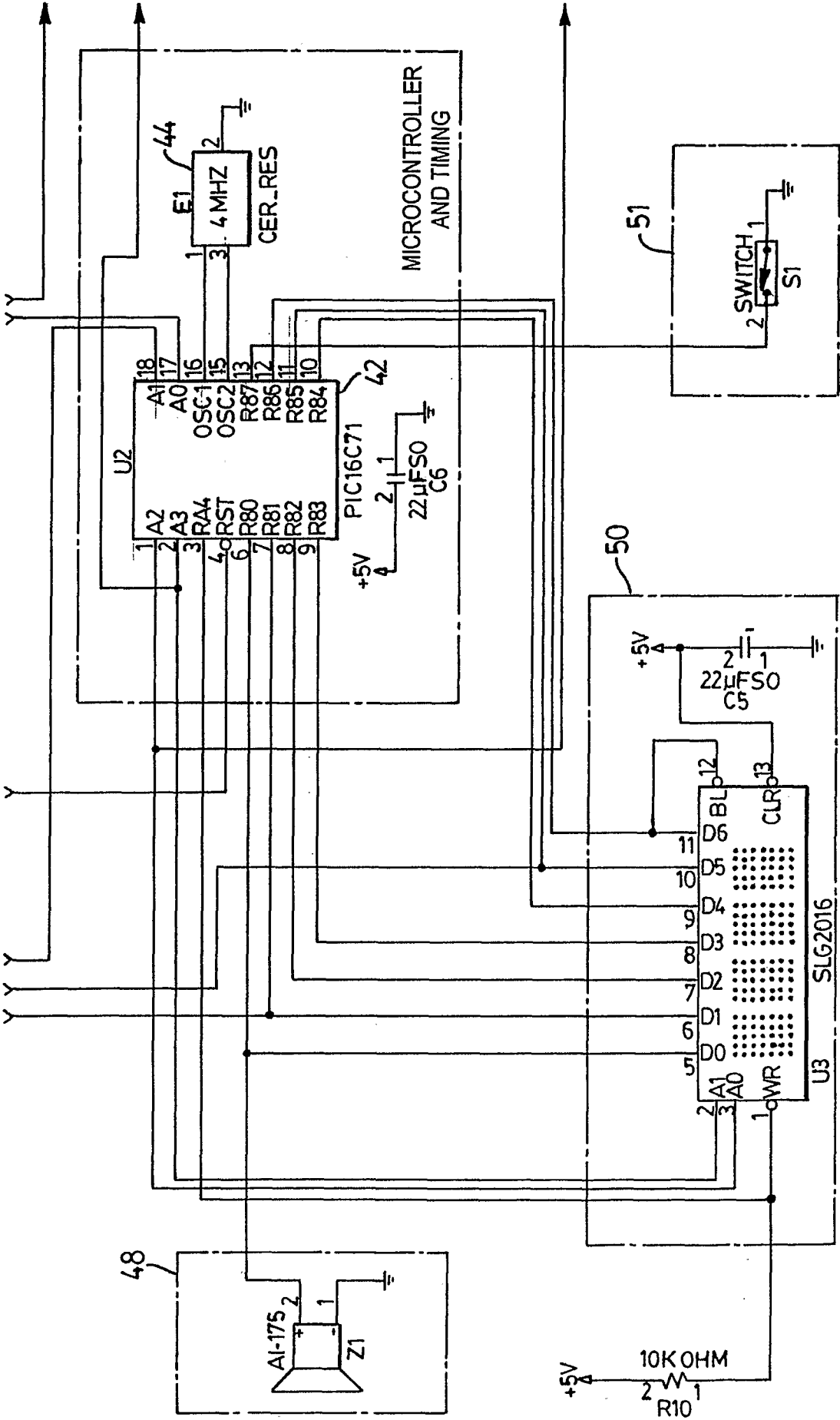


FIG. 7-2

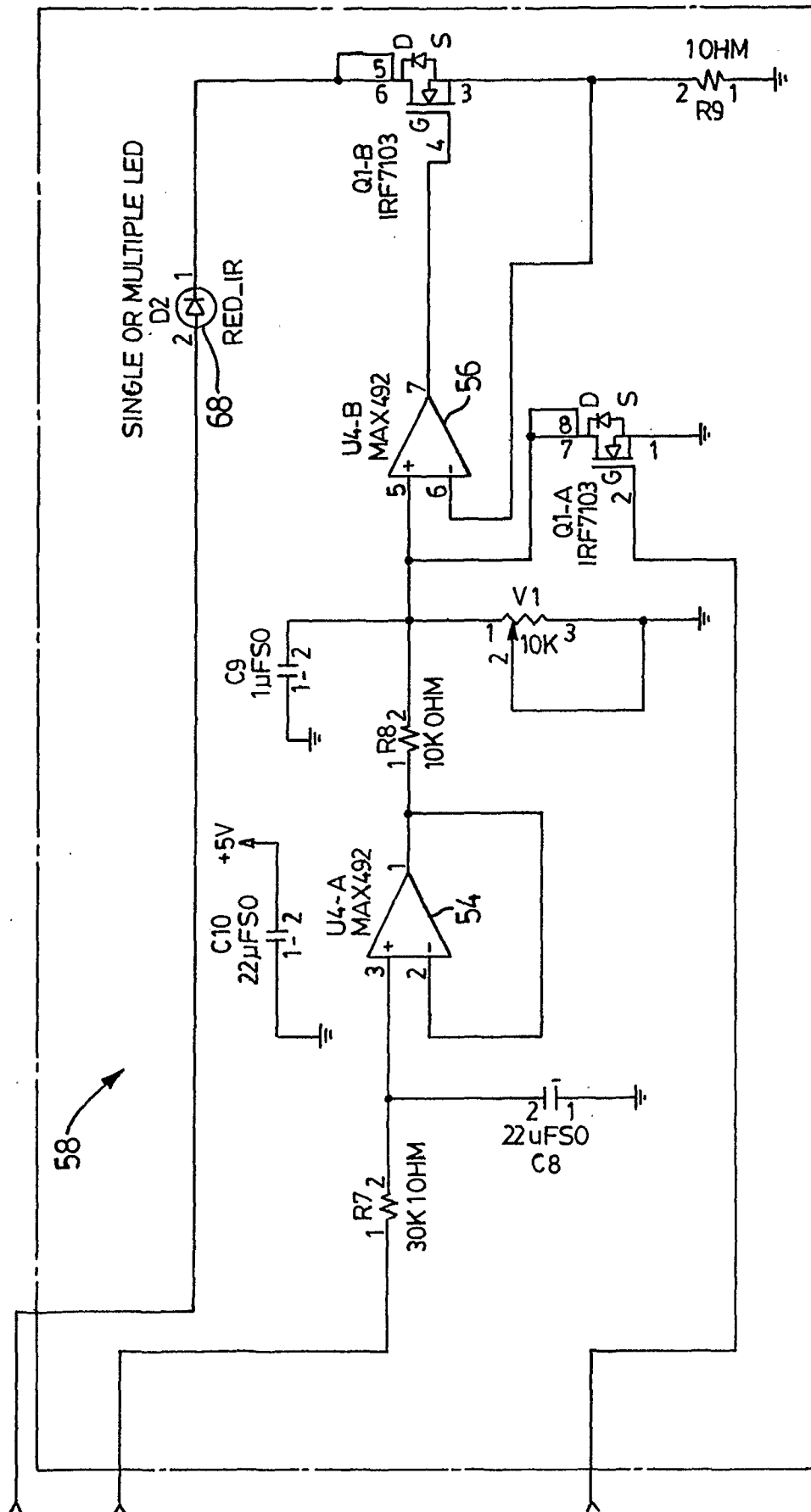


FIG. 7-3

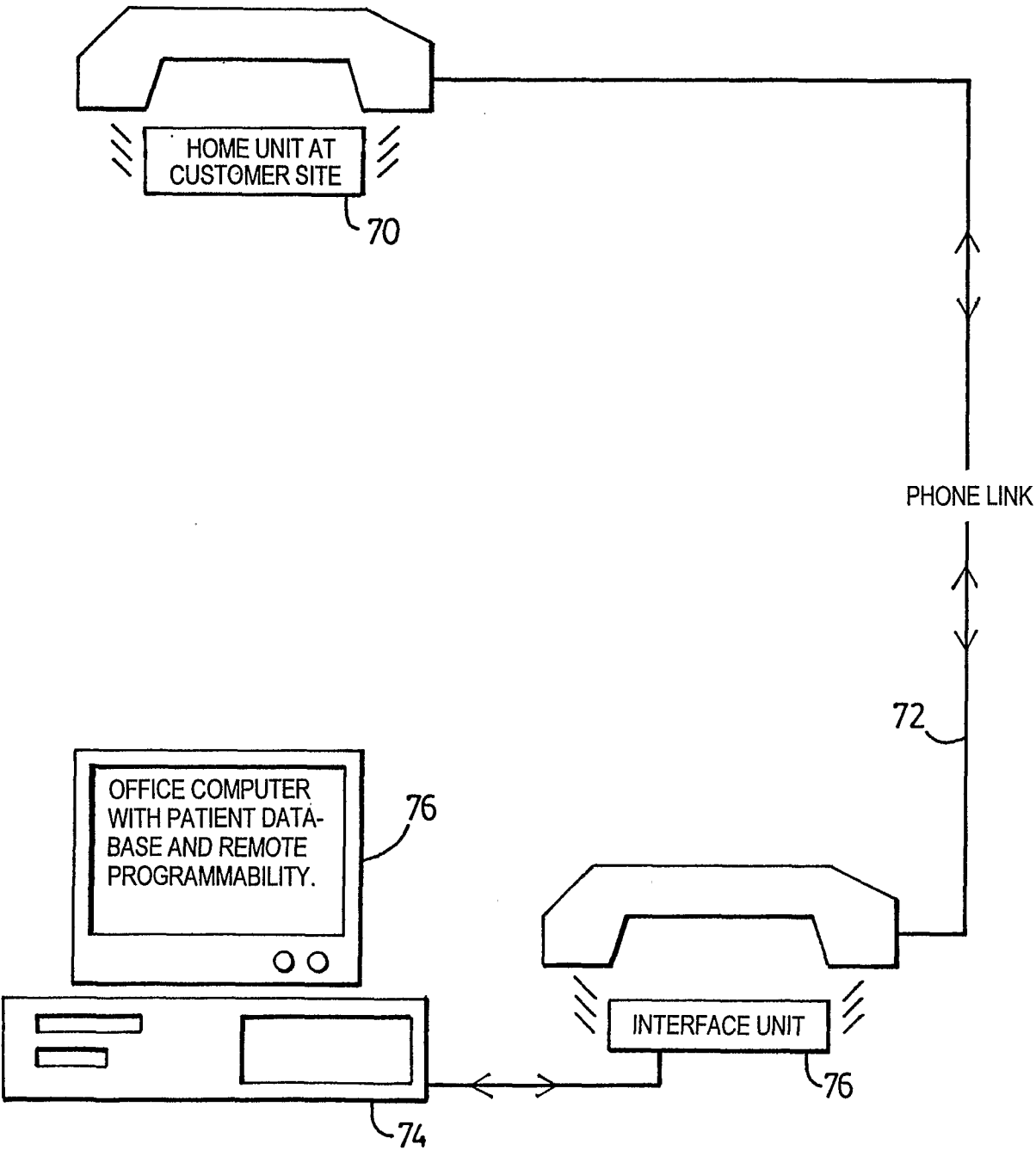


FIG. 8

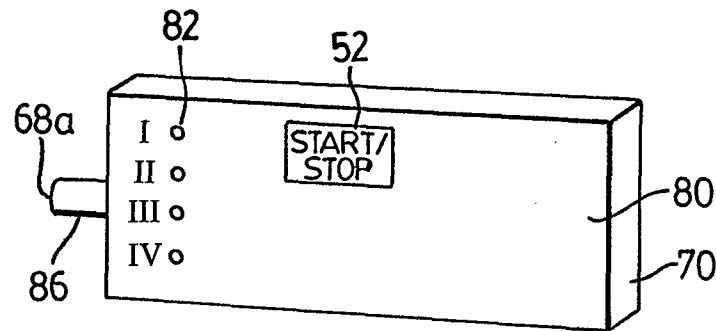


FIG. 9

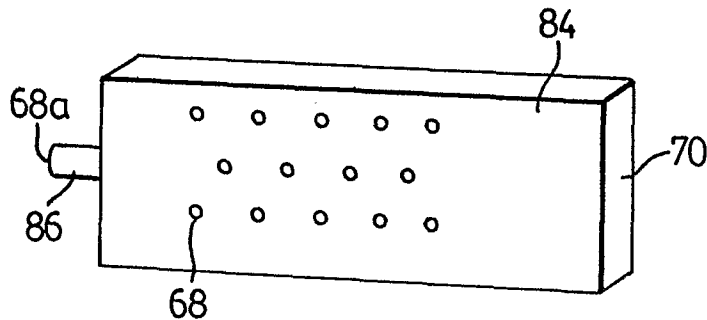


FIG. 10

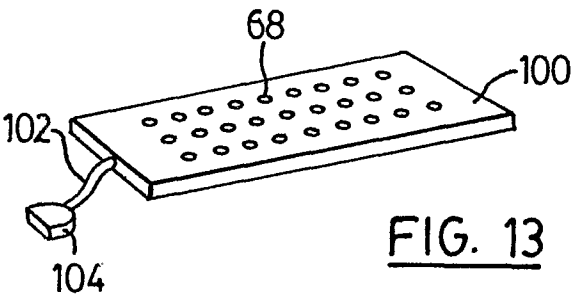


FIG. 13

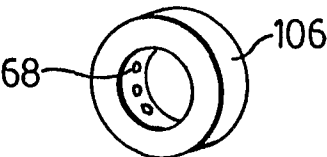


FIG. 14

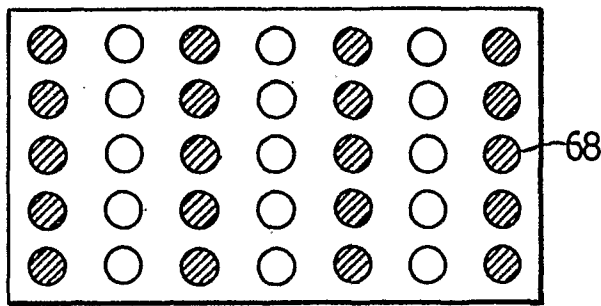


FIG 11a

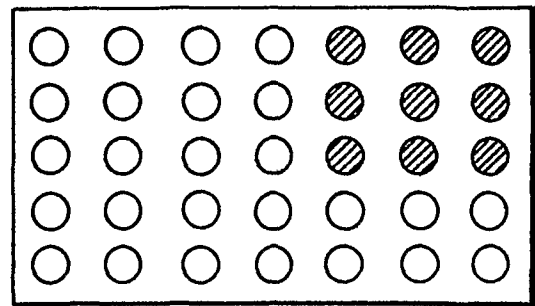


FIG. 11b

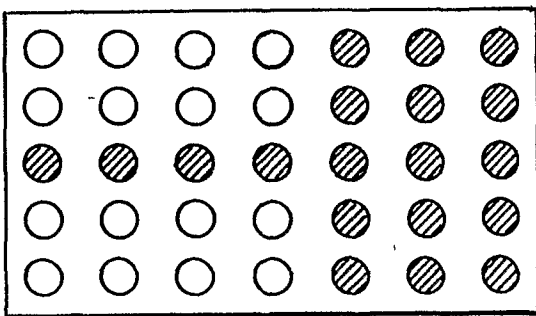


FIG. 11c

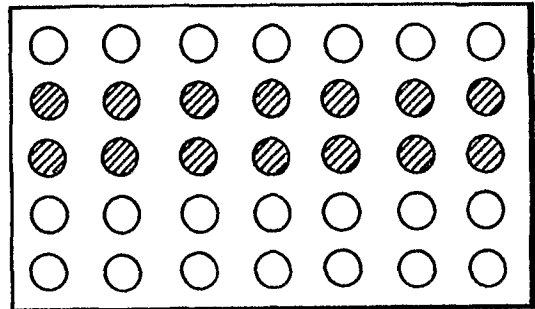


FIG. 11d

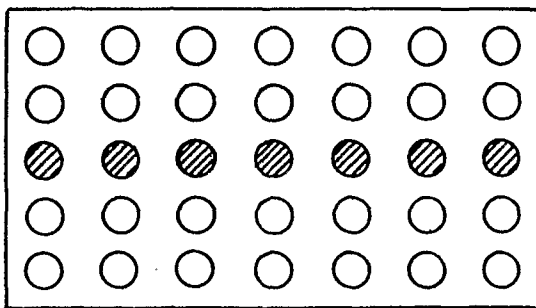


FIG 11e

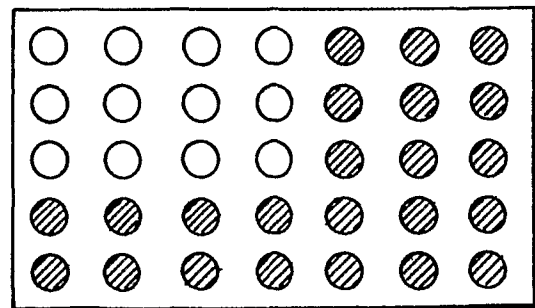
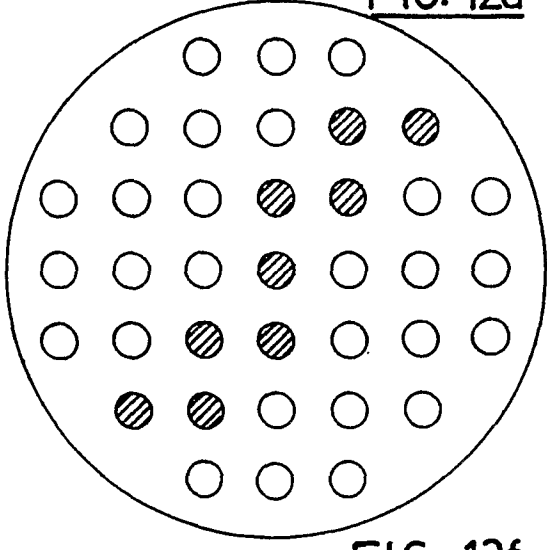
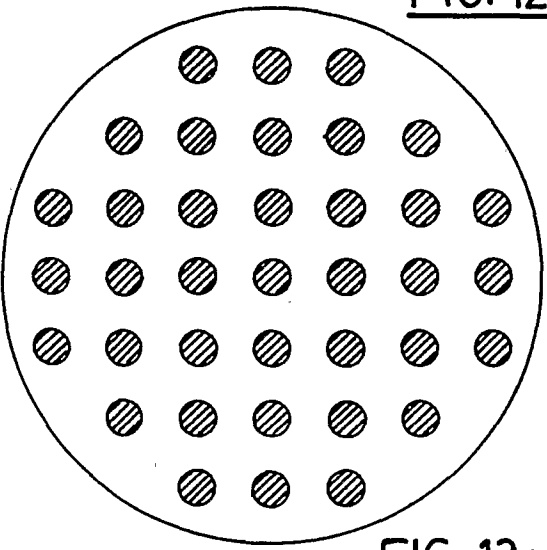
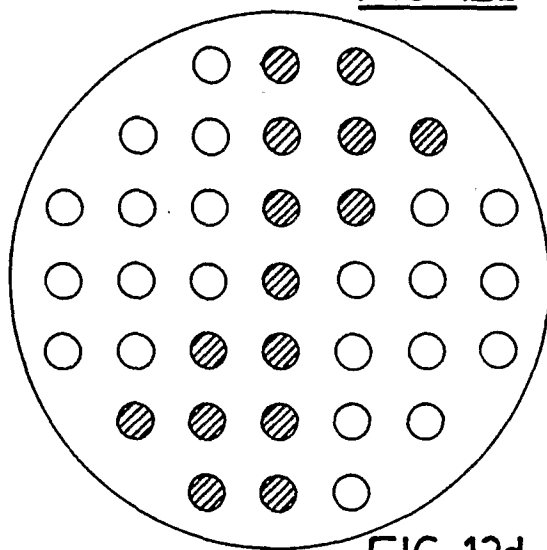
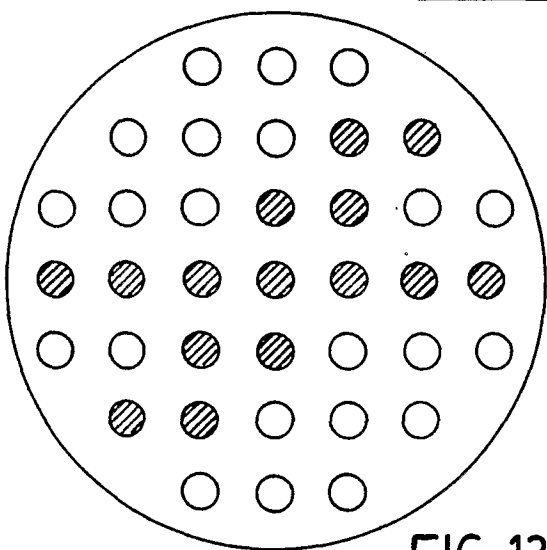
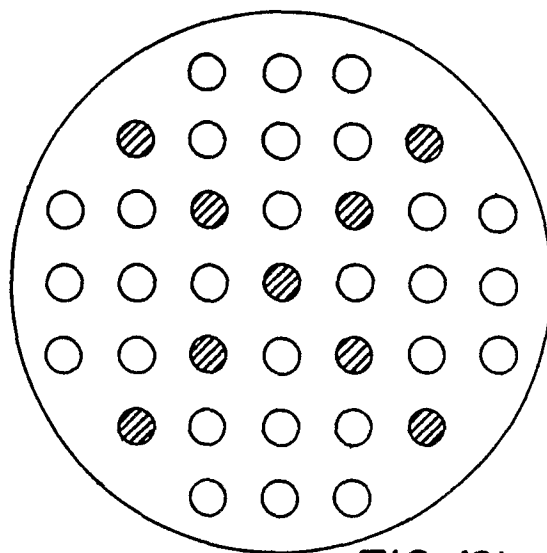
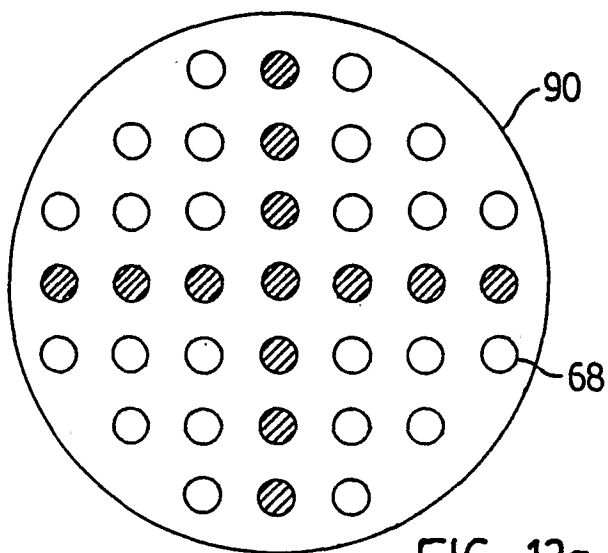


FIG. 11f

LEGEND: ○ OFF
 ● ON

LEGEND: ○ OFF ● ON



INTERNATIONAL SEARCH REPORT

International Application No

PCT/CA 00/00081

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 616 140 A (PRESCOTT MARVIN) 1 April 1997 (1997-04-01) column 3, line 5 - line 46 column 5, line 31 - column 6, line 9 column 9, line 51 - line 64 column 14, line 50 - line 63 ----	1-6, 10-22, 26-42, 44, 48, 49
X	WO 98 20937 A (CAMPBELL IAIN ;KAHN FRED (CA); MEDITECH INTERNATIONAL INC (CA); ST) 22 May 1998 (1998-05-22) page 5, line 11 - line 19 page 11, line 24 - line 26 page 13, line 17 - line 19 page 20, line 9 - page 22, line 3; figures 33-39 ----- -/--	1-6, 8, 12-14, 16, 17, 44, 47-49

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

14 September 2000

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Petter, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 00/00081

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 674 468 A (SYNTON GMBH FORSCHUNG ENTWICKL) 27 September 1995 (1995-09-27) column 1, line 27 - line 50 ----	10, 11
A	EP 0 320 080 A (ALEXANDROU ALEX PANIKOS ;DIAMANTOPOULOS COSTAS (GB)) 14 June 1989 (1989-06-14) page 6, line 24 - line 54 page 7, line 53 -page 8, line 14 ----	15, 18, 31
A	DE 41 08 328 A (DURANGO HOLDING GMBH) 17 September 1992 (1992-09-17) column 1, line 3 - line 31 column 1, line 61 -column 2, line 4; claim 1 column 2, line 30 - line 32 ----	18
A	US 5 752 976 A (DUFFIN EDWIN G ET AL) 19 May 1998 (1998-05-19) abstract -----	7, 9, 23, 25, 45, 46

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 00/00081

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5616140	A	01-04-1997	AU	2104195 A	09-10-1995
			WO	9525563 A	28-09-1995
			US	5989245 A	23-11-1999
WO 9820937	A	22-05-1998	AU	4938897 A	03-06-1998
			BR	9712948 A	28-03-2000
			CA	2210450 A	13-05-1998
			EP	0951314 A	27-10-1999
EP 0674468	A	27-09-1995	DE	9417441 U	12-01-1995
EP 0320080	A	14-06-1989	US	4930504 A	05-06-1990
			AT	92351 T	15-08-1993
			CA	1329416 A	10-05-1994
			DE	3882933 A	09-09-1993
			IN	167659 A	01-12-1990
			JP	1136668 A	29-05-1989
			JP	2690952 B	17-12-1997
DE 4108328	A	17-09-1992	NONE		
US 5752976	A	19-05-1998	AU	709767 B	09-09-1999
			AU	6176996 A	22-01-1997
			CA	2224520 A	09-01-1997
			EP	0939662 A	08-09-1999
			JP	11508165 T	21-07-1999
			WO	9700708 A	09-01-1997
			US	6083248 A	04-07-2000

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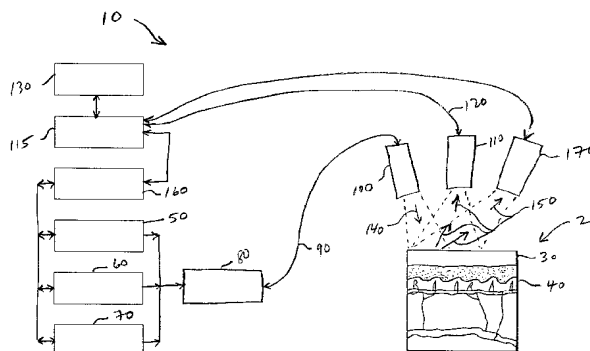
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(54) Title: **PHOTOSTIMULATON TREATMENT APPARATUS AND METHODS FOR USE**



(57) **Abstract:** A therapeutic treatment apparatus (10) for photostimulation of biological tissue (20, 30, 40) that includes at least one treatment radiation source source (50) configured to radiate energy at a predetermined wavelength selected from the range approximately between 400 and 1,500 nanometers and adapted to illuminate the biological tissue (20, 30, 40). The apparatus further incorporates an infrared camera (110) configured to detect infrared radiation and adapted to produce image signals corresponding to the detected radiation. A data processing and recording device (115) is also included that is capable of receiving and processing the image signals and is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device (115) is also configured to capture and analyze the frames to quantify the radiation emitted by the biological tissue in units of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. The data processing and recording device (110) is also configured to detect, block, and/or subtract the energy emitted from the radiation source (50) that is reflected by the target (20, 30, 40) when quantifying the energy emitted by the biological tissue (20, 30, 40) sans the reflected energy. A method for using the device (10) is also described.

WO 01/78830 A2

PHOTOSTIMULATION TREATMENT APPARATUS AND METHODS FOR USE**Technical Field**

This invention relates to an apparatus for treating various biological tissues and biomedical conditions in mammals with a photostimulation device that is precisely controlled
5 using, in part, a high-precision temperature monitoring device such as a thermographic diagnostic device.

Background of the Invention

The treatment of various biomedical conditions in mammals have been treated by
10 physicians and therapists using a wide variety of photostimulation devices. Many such devices are configured to emit radiation having visible and infrared wavelengths (approximately between 400 to 11,500 nanometers) as it has been shown that therapeutic benefits may result from irradiating biological tissue with certain wavelengths of radiation for various periods of time. In various surgical applications, photostimulation devices are configured to emit radiation
15 outside the visible and near-infrared ranges described above to induce photoablation of various tissues, which, depending upon the type of resulting effect, is also referred to by those with skill in the art as ablation, vaporization, ionization, and destruction. In both surgical and therapeutic applications, various attempts have been made to monitor the temperature of the biological tissues subject to the incident radiation so that minimum and maximum energy input to the
20 biological tissues can be induced and/or maintained.

In any application of photostimulation techniques to biological tissue, various incident radiation parameters are to be selected, adjusted, and monitored including the wave length, energy, pulse duration (including a continuous pulse), divergence of the incident radiation beam, and luminosity. In the past, a wide variety of focusing and defocusing optics have been used to establish a quantified cross-sectional area of the incident radiation beam at the point along a beam axis that intersects the upper surface of the biological tissue. By selecting, monitoring, and controlling at least these parameters, then the user can control the effects on the target biological tissue from the incident radiation, which effects include thermal effects such as vaporization, ionization, heating by phonon absorption, and atomic and molecular electronic, rotational, and vibrational excitation.

In therapeutic applications, it is desirable to induce only so much energy of a selected wavelength on the biological tissue whereby certain desirable effects can be induced. These effects typically do not irradiate the target with enough energy to cause vaporization and/or ionization. However, in most therapeutic applications, the biological tissue is irradiated with enough energy to induce the desired therapeutic effect, which can include photocoagulation as well as less damaging thermal effects such as denaturing of the tissue proteins. Even less damaging effects can also be initiated that include photostimulated biochemical changes induced by electronic, rotational, and vibrational excitation of the various constituents of the target biological tissue. At least one study has attempted to classify the various optical properties of human tissue. See, e.g., p. 1386, Parrish, J.A., Deutsch, T. F., *Laser Photomedicine*, I.E.E.E. J. of Quantum Electronics, Vol. QE-20, No. 12, 12/1984; Meyer, R. A., et al., *A Laser Stimulator for the Study of Cutaneous Thermal and Pain Sensation*, I.E.E.E. Transactions on Biomedical Engineering, Vol. BME-23, No. 1, pp. 54-60, 1/1976; *A Brief Report, and Some Abstracts from the International Discussions of Laser Applications in*

Medicine, Paris, 7-8 July 1969, Medical and Biological Engineering, Vol. 8, pp. 427-430, Pergamon Press, 1970, Great Britain.

Various photostimulation devices have been taught in the prior art that are configured for irradiating and/or ablating target biological tissue. U.S. Pat. No. 5,346,488 to Prince et al. is limited to ablation of atherosclerotic plaque using short-duration laser pulses. U.S. Pat. Nos. 5,112,328; 5,196,004; 5,520,697; and 5,540,676 are directed to laser-based surgical devices that incorporate one or more laser radiation sources emitting electromagnetic radiation having one or more wavelengths and which are adapted to be used in various photomedicinal applications. U.S. Pat. No. 5,150,704 is directed to a device that incorporates multiple radiation sources for irradiating selected body parts with a plurality of laser probes. U.S. Pat. Nos. 4,854,320 and 5,002,051 are both limited to irradiation of laser energy to cause the denaturing of collagenous proteins of biological tissue to produce a biological glue to purportedly improves healing of wounds. Other examples of laser-based photostimulation devices configured for use in a variety of surgical and therapeutic applications include U.S. Pat. Nos. 4,573,465; 4,966,144; 5,161,526; 5,409,482; 5,445,146; 5,527,350; and 5,951,596; French Pat. Nos. 2,458,272; 2,561,515; 2,577,425; German Pat. Nos. 2,820,908; 3,401,492; and U.S.S.R. Pat Nos. 871,802; 1,242,187; 1,771,762; and 1,782,617.

None of these references disclose, teach, suggest, or provide any motivation for incorporating energy management devices that can precisely measure the actual amount of energy absorbed by the target biological tissue. In the applications described in the prior art where certain predetermined dosages of energy were to be applied to the target biological tissue, the radiation source and the method of its use to irradiate the target biological tissue was preconfigured to operate at a preselected wavelength, energy output, pulse rate, frequency, and/or exposure time.

Various types of temperature measuring devices exist. However, very few of the temperature measurement devices available in the prior art are suitable for use for purposes of the present invention. The prior art describes various types of temperature measurement devices. In most applications, surface contact thermistors and/or thermometers are used to measure the surface temperature of the target biological tissue. However, these types of devices are unsuitable for purposes of the present invention because they cannot be moved in real-time in applications where the target biological tissue includes a wide area that is irradiated in sections that are changed or rotated over some time interval. Additionally, the presence of a contact temperature measurement can interfere with the desired irradiation treatment modality.

U.S. Pat. Nos. 5,115,815; 5,386,117; 5,458,418; 5,467,126; 5,595,444; and 5,637,871 disclose various non-contact devices that are configured to measure the temperature of a target surface using various types of infrared radiation detection devices that operate using well-known thermography principles. Despite the capabilities of the various systems disclosed in the prior art, none the references discloses, suggests, or describes any motivation to use the thermography devices in accordance with the aspects of the present invention.

What has been needed but unavailable in the prior art is the accurate, real-time detection of temperature during treatment of a target biological tissue using surgical and therapeutic photostimulation devices. In particular, what has been needed is a photostimulation device and method for use that can impart a precisely controlled amount of energy to a target biological tissue and that can simultaneously, continuously, and precisely monitor the energy imparted to the target tissue. Accordingly, the present invention discloses an apparatus and a method for use that incorporates these and other capabilities.

SUMMARY OF THE INVENTION

In general, the present invention relates to an apparatus, and a method for using it, that is directed to the photostimulation of biological tissue such as, for example without limitation, cutaneous and subcutaneous biological tissues. Many types of electromagnetic radiation sources, guides, projectors, detectors, and controllers are available that are suitable for purposes of the present invention. The apparatus includes a therapeutic treatment apparatus for photostimulation of biological tissue that includes at least one treatment radiation source that is configured to emit radiation at a predetermined wavelength selected from the range of approximately between 400 and 11,500 nanometers.

The treatment radiation source may be one of a plurality of sources each configured to emit radiation at one or more wavelengths including, for purposes of illustration but not limitation, the above described range. In configurations where more than one treatment radiation source is used, then the sources are preferably coupled to an optical coupler. The coupler is further coupled to a radiation guide such as a fiber optic guide adapted to communicate the radiation of the treatment source or sources.

Preferably, the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes ("SSD"). More preferably, the at least one treatment radiation source is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers. Even more preferably, the at least one treatment radiation source is a neodymium-yttrium-aluminum-garnet ("Nd:YAG") laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

The fiber optic guide may be further connected to a radiation focusing device such as a radiation emitting probe or wand that can be manipulated by a user for purposes of irradiating the target biological tissue. Each of the treatment radiation sources may

alternatively be coupled to additional, independent wands or probes via additional, separate fiber optic cables.

For configurations of the present that employ treatment radiation that is invisible to the unaided human eye, an additional radiation source configured to emit radiation in the visible spectrum may be coupled to the previous treatment radiation sources to operate as an aiming radiation source. Alternatively, the aiming radiation source may be coupled to each of the radiation sources that are independently coupled to separate wands or probes. In other variations, additional aiming radiation sources may be used to emit radiation at various visible wavelengths of light so that multiple aiming radiation wavelengths may be employed and coupled to selected treatment radiation sources. For example, visible blue light may indicate treatment radiation of a first wavelength, while visible red light may be used to indicate a different treatment radiation wavelength, and other colors may be used to indicate other types of treatment radiation. Alternatively, multiple different wavelengths of aiming radiation may be used to indicate modes of operation. For example, power settings below a certain predetermined threshold may be identified by visible red light, while higher power settings may be indicated using visible blue light.

The present invention also incorporates a video-type camera that is preferably configured to detect infrared radiation having a wavelength approximately between 700 and 20,000 nanometers. The camera is further preferably adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is also included in the present invention, which is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of digitally encoded frames corresponding to the image signals. The data processing and recording device preferably captures and analyzes the frames. In analyzing the frames, the data processing and recording device is configured to quantify the radiation emitted by the

biological tissue in units of measurement selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

5 The data processing and recording device may also include a memory or storage component capable of temporarily and/or permanently storing the image signals, electronic signals, and/or frames to any of a number of such components including, for example but not for limitation, random access memory, floppy disks, CD-ROMs, conventional hard disks, analog or digital video tape, and any other type of readily available storage media that is
10 presently available for such purposes.

 In a variation of the preceding embodiment, the therapeutic treatment apparatus for photostimulation of biological tissue incorporates at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue. In a
15 further variation, the data processing and recording device is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals. Preferably, the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in units of measurement selected from the group
20 described above. More preferably, the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

 The present invention also contemplates a variation wherein the data processing and recording device is configured to measure the temperature of the biological tissue and to

control the output of the at least one treatment radiation source whereby the biological tissue is heated to and maintained at a predetermined temperature for a selected period of time.

In another variation of the instant invention, the therapeutic treatment apparatus for photostimulation of biological tissue is modified wherein the data processing and recording
5 device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure.

The present invention is also directed to a variation wherein the data processing and recording device is further configured to control the energy output of the at least one
10 treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

In yet another variation of the present invention, a therapeutic treatment apparatus for photostimulation of biological tissue includes at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately
15 between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation and further including a filter component adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic
20 filters. This variation further incorporates a data processing and recording device that is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the
25 group including wavelength, radiance, luminosity, area, volume, temperature, change in

temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In an alternative configuration, the instant invention contemplates a therapeutic treatment apparatus for photostimulation of biological tissue that incorporates at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. This configuration includes an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation at windows corresponding to precise moments in time. A data processing and recording device is also incorporated that is capable of receiving and processing the image signal, and which is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device in this alternative configuration is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. This configuration of the data processing and recording device is further modified to control the infrared camera and the energy output of the at least one treatment radiation source to emit pulses of radiation to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy. Lastly, the data processing and recording device is further configured to block the detection of treatment radiation reflected by the biological tissue by synchronizing the timing the emitted treatment radiation pulses with the infrared camera detection windows so that the camera captures an image of the radiation emitted by the target biological tissue at a moment between radiation pulses.

The present invention also contemplates a method for use of a therapeutic treatment apparatus for photostimulation of biological tissue that includes the steps of selecting at least one treatment radiation source that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is the step of selecting an infrared camera that is configured to detect infrared radiation emitted by the target biological tissue, the camera being adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is selected that is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device captures and analyzes the frames and also quantifies the radiation emitted by the biological tissue. The radiation is quantified in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In a variation of the preceding method, the method further includes the steps of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue; blocking the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtracting the reflected energy from quantified unit of measure; and controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

Brief Description of the Drawing

Without limiting the scope of the present invention as claimed below and referring now to the drawings, wherein like reference numerals and numerals with primes across the several views refer to identical, corresponding, or equivalent features and parts:

5 Figure 1 is a schematic representation of the various elements of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The therapeutic treatment apparatus of the present invention is generally configured for photostimulation of biological tissue. The apparatus includes at least one treatment
10 radiation source adapted to radiate electromagnetic energy at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers. The apparatus further incorporates an infrared camera configured to precisely and continuously detect infrared radiation. The camera is adapted to produce image signals corresponding to the detected radiation. A data processing and recording device is also included that is capable of
15 receiving and processing the image signals. The data processing and recording device is further adapted to generate an electronic signal in the form of a plurality of digital frames that correspond to the image signals. The data processing and recording device is also configured to capture and analyze the frames and to quantify the radiation emitted by the biological tissue. The radiation is quantified in units of measurement selected from the group including
20 wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy. The data processing and recording device is also configured to detect and/or block the energy emitted from the at least one treatment radiation source that is reflected by the target biological tissue. The therapeutic treatment apparatus is also
25 configured to quantify the energy emitted by the biological tissue by blocking or subtracting

the reflected energy from the quantified result. A method for using the device in its multiple configurations, variations, modifications, and alternatives is also disclosed.

Referring now to FIG. 1, the present invention relates to an apparatus **10**, and a method for using it, that is directed to the photostimulation of biological tissue **20** such as, for example without limitation, cutaneous and subcutaneous biological tissues **30, 40**. Many types of electromagnetic radiation sources, guides, projectors, detectors, and controllers are available that are suitable for purposes of the present invention. Many such devices that include such components are disclosed in co-owned U.S. patent application serial no. 09/281,443, filed on March 29, 1999, now U.S. Pat. No. _____, and in U.S. Pat. Nos. 4,573,465; 4,966,144; 5,002,051; 5,049,147; 5,112,328; 5,139,494; 5,150,704; 5,445,146; 5,527,350; 5,540,676; 5,755,752; and 5,951,596, each of which are hereby incorporated by reference in their entirety.

The apparatus of the instant includes a therapeutic treatment apparatus for photostimulation of biological tissue that includes at least one treatment radiation source **50** that is configured to emit radiation at a predetermined wavelength selected from the range of approximately between 400 and 11,500 nanometers.

The treatment radiation source **50** may be one of a plurality of sources **50, 60, 70** each configured to emit radiation at one or more wavelengths including, for purposes of illustration but not limitation, the above described range. In configurations where more than one treatment radiation source is used, then the sources **50, 60, 70** are preferably coupled to an optical coupler **80**. The coupler **80** is further coupled to a radiation guide **90** such as a fiber optic guide adapted to communicate the radiation of the treatment source or sources.

Preferably, the at least one treatment radiation source **50** is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes ("SSD"). More preferably, the at least one treatment radiation source

50 is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers. Even more preferably, the at least one treatment radiation source **50** is a neodymium-yttrium-aluminum-garnet (“Nd:YAG”) laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

5 The fiber optic guide **90** may be further connected to a radiation focusing device such as a radiation emitting probe or wand **100** that can be manipulated by a user for purposes of irradiating the target biological tissue **20**. Each of the treatment radiation sources **50**, **60**, **70** may alternatively be coupled to additional, independent wands or probes via additional, separate fiber optic cables (not shown).

10 For configurations of the present that employ treatment radiation that is invisible to the unaided human eye, an additional radiation source configured to emit radiation in the visible spectrum, such as for example, source **70**, may be coupled to the previous treatment radiation sources **50**, **60** to operate as an aiming radiation source. Alternatively, the aiming radiation source **70** may be coupled to each of the radiation sources **50**, **60** that are

15 independently coupled to separate wands or probes similar to probe **100**. In other variations, additional aiming radiation sources (not shown) may be used to emit radiation at various visible wavelengths of light so that multiple aiming radiation wavelengths may be employed and coupled to selected treatment radiation sources. Alternatively, the radiation emitted by aiming source **70** may be split and coupled to various probes. For example, visible blue light
20 may indicate treatment radiation of a first wavelength, while visible red light emitted by a separate source may be used to indicate a different treatment radiation wavelength, and other colors may be used to indicate other types of treatment radiation. Alternatively, multiple different wavelengths of aiming radiation may be used to indicate modes of operation. For example, power settings below a certain predetermined threshold may be identified by visible
25 red light, while higher power settings may be indicated using visible blue light.

The present invention also incorporates a video-type infrared camera **110** that is preferably configured to detect infrared radiation having a wavelength approximately between 700 and 20,000 nanometers. The camera **110** is further preferably adapted to produce image signals corresponding to the detected radiation. A data processing and recording device **115** is also included in the present invention, which is coupled by signal line **120** to the camera **110** and which is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of digitally encoded frames corresponding to the image signals. The data processing and recording device **115** preferably captures and analyzes the frames. In analyzing the frames, the data processing and recording device **115** is configured to quantify the radiation emitted by the biological tissue **20** in units of measurement selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

The data processing and recording device **115** may also include a memory or storage component (not shown but known to those with skill in the art) capable of temporarily and/or permanently storing the image signals, electronic signals, and/or frames to any of a number of such components including, for example but not for limitation, random access memory, floppy disks, CD-ROMs, conventional hard disks, analog or digital video tape, and any other type of readily available storage media **130** that is presently available for such purposes.

In a variation of the preceding embodiment, the therapeutic treatment apparatus **10** for photostimulation of biological tissue incorporates at least one treatment radiation source **50** providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue **20**. In a further variation, the data processing and recording device **115** is configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a

plurality of frames corresponding to the image signal at various time intervals. Preferably, the data processing and recording device **115** captures and analyzes the frames to quantify the radiation emitted by the biological tissue **20** in units of measurement selected from the group described above. More preferably, the data processing and recording device **115** is further
5 configured to control the energy output **140** of the at least one treatment radiation source **50** to induce and maintain a preselected energy input to and output from the biological tissue **20**.

The present invention also contemplates a variation wherein the data processing and recording device **115** is configured to measure the temperature of the biological tissue **20** and to control the output of the at least one treatment radiation source **50** whereby the biological
10 tissue **20** is heated to and maintained at a predetermined temperature for a selected period of time.

In another variation of the instant invention, the therapeutic treatment apparatus **10** for photostimulation of biological tissue **20** is modified wherein the data processing and recording device **115** is further configured to block the energy **140** emitted by the at least one
15 treatment radiation source **50** that is reflected by the biological tissue **20** and subtract the reflected energy **150** from quantified unit of measure.

The present invention is also directed to a variation wherein the data processing and recording device **115** is further configured to control the energy output of the at least one treatment radiation source **50** to induce and maintain a preselected energy input to and output
20 from the biological tissue **20** sans the reflected energy **150**. This is accomplished either by configuring the device **115** or by coupling the device **115** with an independent controller **160** configured to communicate with and control the at least one treatment radiation source **50** as well as any additional sources **60, 70**. If desired, a visible light video camera **170** may also be

incorporated into the apparatus of the present invention for purposes of monitoring and / or recording operation of the instant invention.

In yet another variation of the present invention, a therapeutic treatment apparatus **10** for photostimulation of biological tissue **20** includes at least one treatment radiation source **50** providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue **20**. Also included is an infrared camera **110** configured to detect infrared radiation emitted by the target biological tissue **20** and adapted to produce an image signal corresponding to the detected radiation and further including a filter component (not shown) adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic filters. This variation further incorporates a data processing and recording device that is capable of receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal. The data processing and recording device **115** is adapted to capture and analyze the frames to quantify the radiation emitted by the biological tissue **20** in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In an alternative configuration, the instant invention contemplates a therapeutic treatment apparatus **10** for photostimulation of biological tissue that incorporates at least one treatment radiation source **50** providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue **20**. This configuration includes an infrared camera **110** configured to detect infrared radiation **150** emitted by the target biological tissue **20** and adapted to produce an image signal corresponding to the detected radiation **150** at windows corresponding to

precise moments in time. A data processing and recording device **115** is also incorporated that is capable of receiving and processing the image signal, and which is adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal.

The data processing and recording device **115** in this alternative configuration is adapted to

capture and analyze the frames to quantify the radiation emitted by the biological tissue **20** in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

This configuration of the data processing and recording device **115** is further modified to

control the infrared camera **110** and the energy output of the at least one treatment radiation source **50** to emit pulses of radiation **140** to induce and maintain a preselected energy input to and output from the biological tissue **20** sans the reflected energy **150**. Lastly, the data processing and recording device **115** is further configured to block the detection of treatment radiation **150** reflected by the biological tissue **20** by synchronizing the timing the emitted treatment radiation pulses with the infrared camera detection windows so that the camera **110** captures an image of the radiation being emitted by target biological tissue **20** at a moment between radiation pulses.

The present invention also contemplates a method for use of a therapeutic treatment apparatus for photostimulation of biological tissue **20** that includes the steps of selecting at least one treatment radiation source **50** that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue. Also included is the step of selecting an infrared camera **110** that is configured to detect infrared radiation emitted by the target biological tissue **20**, the camera **110** being adapted to produce image signals corresponding to the detected radiation.

A data processing and recording device **115** is selected that is capable of receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals. The data processing and recording device **115** captures and analyzes the frames and also quantifies the radiation **150** emitted by the biological tissue **20**. The radiation is quantified in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

In a variation of the preceding method, the method further includes the steps of controlling the energy output of the at least one treatment radiation source **50** to induce and maintain a preselected energy input to and output from the biological tissue **20**; blocking the energy emitted by the at least one treatment radiation source **50** that is reflected by the biological tissue **20** and subtracting the reflected energy from quantified unit of measure; and controlling the energy output of the at least one treatment radiation source **50** to induce and maintain a preselected energy input to and output from the biological tissue **50** sans the reflected energy **150**.

The present invention establishes a significant advance over the previously known devices and methods and the advance is achieved with improved accuracy, simplicity, and without any significant increase complexity of technology.

Thermography is a preferred technique for detecting soft tissue anomalies occurring in various types of biological tissues. Anomalous tissues often experience an altered blood flow circulation. One of the most prominent indicators of anomalies such as inflammation and other injuries is heat, which is due to increased blood circulation. A medical thermogram is a methodology, which allows the detection of such biological soft tissue anomalies by measuring the surface temperature of the target biological tissue.

Thermography is a noninvasive diagnostic application that uses infrared radiation detection technology to quantify the surface temperatures of the target biological tissue and subjacent structures. By converting thermal emissions into a multi-colored "map" wherein various colors correspond to certain wavelengths of emitted radiation, temperature differences as small as approximately between 0.05 and 0.08 degrees Celsius can be detected. In addition to detecting increased heat radiation of target biological tissues, the thermographic techniques of the present invention also contemplate detection of areas where blood circulation is decreased. This can occur where anomalies exist such as nerve damage, a blood clot, and development of subjacent scar tissue. In these anomalous biological tissues regions, the thermographic image may depict cooler than expected temperatures, such as may be expected in tissues that suffer from the initial stages of atrophy or other form of deterioration. It will be understood by those with skill in the art that pathologies of the cutaneous and subcutaneous structures including, for example, tendons, ligaments may be identifiable through identification of the "hot spots" and "cool spots" that while invisible to the unaided human eye, are prominently revealed by thermography. Such anomalous biological tissues can thus be detected as far in advance as two weeks before the onset of clinically detectable signs of injury and/or anomaly.

Various types of thermographic cameras, signal processing, and analysis equipment are known in the prior art that includes U.S. Pat. Nos. 5,959,444; 5,467,126; 5,637,871; and 5,386,117. Vendors known to have cameras and related equipment that are suitable for purposes of use with the present invention include Sierra Pacific Innovations #2, www.x20.org, 1034 Emerald Bay Rd., Dept. 437, South Lake Tahoe, California; Rod Hall International, Inc., www.rodhall.com, 1360 Kleppe Lane, Sparks, Nevada; Microlytics, Inc., www.endeavorship.com, P.O. Box 2022, Stillwater, Oklahoma; Raytheon Systems Company, www.raytheoninfrared.com, 6380 Hollister Avenue, Goleta, California; Infrared Components

Corporation, www.infraredcomponents.com, 2306 Bleecker Street, Utica, New York; and Indigo Systems Corporation, www.indigosystems.com/cameras.html, 5385 Hollister Ave #103, Santa Barbara, California.

Numerous modifications and variations of the preferred embodiments disclosed herein

5 will be apparent to those skilled in the art. For example, although specific embodiments have been described in detail, those with skill in the art can understand that the preceding embodiments and variations can be modified with various types of treatment radiation sources and thermographic camera and data processing devices for desired compatibility with the wide variety of modalities presently in use for photostimulation of biological tissues.

10 Accordingly, even though only few variations of the present invention are described herein, it is to be understood that the practice of these additional modifications and variations and the equivalents thereof, are within the spirit and scope of the invention as defined in the following claims.

WE CLAIM:

1. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source emitting a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to irradiate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce image signals corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals; and

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

2. The therapeutic treatment apparatus of Claim 1, wherein the data processing and recording device records only temporarily.

3. The therapeutic treatment apparatus of Claim 1, wherein the data processing and recording device is further configured to quantify the radiation emitted by the biological tissue in units of measurement selected from the group including area and volume.

4. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

5. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

6. The therapeutic treatment apparatus of Claim 1, wherein the at least one treatment radiation source is configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

7. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement

selected from the group including wavelength, radiance, luminosity, temperature, area, volume, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy; and

wherein the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

8. The therapeutic treatment apparatus of Claim 7, wherein the data processing and recording device is configured to measure the temperature of the biological tissue and to control the output of the at least one treatment radiation source whereby the biological tissue is heated to and maintained at a predetermined temperature for a selected period of time.

9. The therapeutic treatment apparatus of Claim 7, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

10. The therapeutic treatment apparatus of Claim 7, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

20

11. The therapeutic treatment apparatus of Claim 7, further comprising:
at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

12. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and

5 adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

10 a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, 15 temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy; and

wherein the data processing and recording device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure.

20

13. The therapeutic treatment apparatus of Claim 12, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes, super-luminous diodes, light emitting devices, and solid-state laser diodes.

14. The therapeutic treatment apparatus of Claim 12, wherein the at least one treatment radiation source is a Nd:YAG SSD laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

5 15. The therapeutic treatment apparatus of Claim 12, further comprising:
at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

10 16. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 800 and 1,100 nanometers and adapted to illuminate the biological tissue;

15 an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames
20 corresponding to the image signal at various time intervals;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature,
25 energy, change in energy, rate of change of energy, and relative energy;

wherein the data processing and recording device is further configured to block the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtract the reflected energy from quantified unit of measure; and

5 wherein the data processing and recording device is further configured to control the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

17. The therapeutic treatment apparatus of Claim 16, wherein the at least one treatment radiation source is selected from the group including semiconductor laser diodes,
10 super-luminous diodes, light emitting devices, and solid-state laser diodes.

18. The therapeutic treatment apparatus of Claim 6, wherein the at least one treatment radiation source is a Nd:YAG laser tuned to emit radiation having a wavelength of approximately 1,064 nanometers.

15

19. The therapeutic treatment apparatus of Claim 16, further comprising:
at least one additional treatment radiation source configured to emit radiation having a wavelength of approximately between 800 and 1,100 nanometers.

20

20. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:
at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation and further including a filter component adapted to block radiation having the predetermined wavelength, the filter selected from the group including optical and electronic
5 filters;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signal; and

wherein the data processing and recording device captures and analyzes the frames to
10 quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

15 21. A therapeutic treatment apparatus for photostimulation of biological tissue, comprising:

at least one treatment radiation source providing radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

20 an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce an image signal corresponding to the detected radiation at windows corresponding to precise moments in time;

a data processing and recording device configured for receiving and processing the image signal and adapted to generate an electronic signal in the form of a plurality of frames
25 corresponding to the image signal;

wherein the data processing and recording device captures and analyzes the frames to quantify the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy;

wherein the data processing and recording device is further configured to control the infrared camera and the energy output of the at least one treatment radiation source to emit pulses of radiation to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy; and

wherein the data processing and recording device is further configured to block the detection of treatment radiation reflected by the biological tissue by synchronizing the timing the emitted treatment radiation pulses with the infrared camera detection windows so that the camera captures an image of the target biological tissue at a moment between radiation pulses.

22. A method for using a therapeutic treatment apparatus for photostimulation of biological tissue, that includes the steps of:

selecting at least one treatment radiation source that provides radiation at a predetermined wavelength selected from the range approximately between 400 and 11,500 nanometers and adapted to illuminate the biological tissue;

selecting an infrared camera configured to detect infrared radiation emitted by the target biological tissue and adapted to produce image signals corresponding to the detected radiation;

selecting a data processing and recording device configured for receiving and processing the image signals and adapted to generate an electronic signal in the form of a plurality of frames corresponding to the image signals; and

capturing and analyzing the frames with the data processing and recording device;

5 and

quantifying the radiation emitted by the biological tissue in at least one unit of measurement selected from the group including wavelength, radiance, luminosity, area, volume, temperature, change in temperature, rate of change of temperature, relative temperature, energy, change in energy, rate of change of energy, and relative energy.

10

23. The method according to Claim 22, further comprising the step of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue.

15

24. The method according to Claim 22, further comprising the step of blocking the energy emitted by the at least one treatment radiation source that is reflected by the biological tissue and subtracting the reflected energy from quantified unit of measure.

20

25. The method according to Claim 22, further comprising the step of controlling the energy output of the at least one treatment radiation source to induce and maintain a preselected energy input to and output from the biological tissue sans the reflected energy.

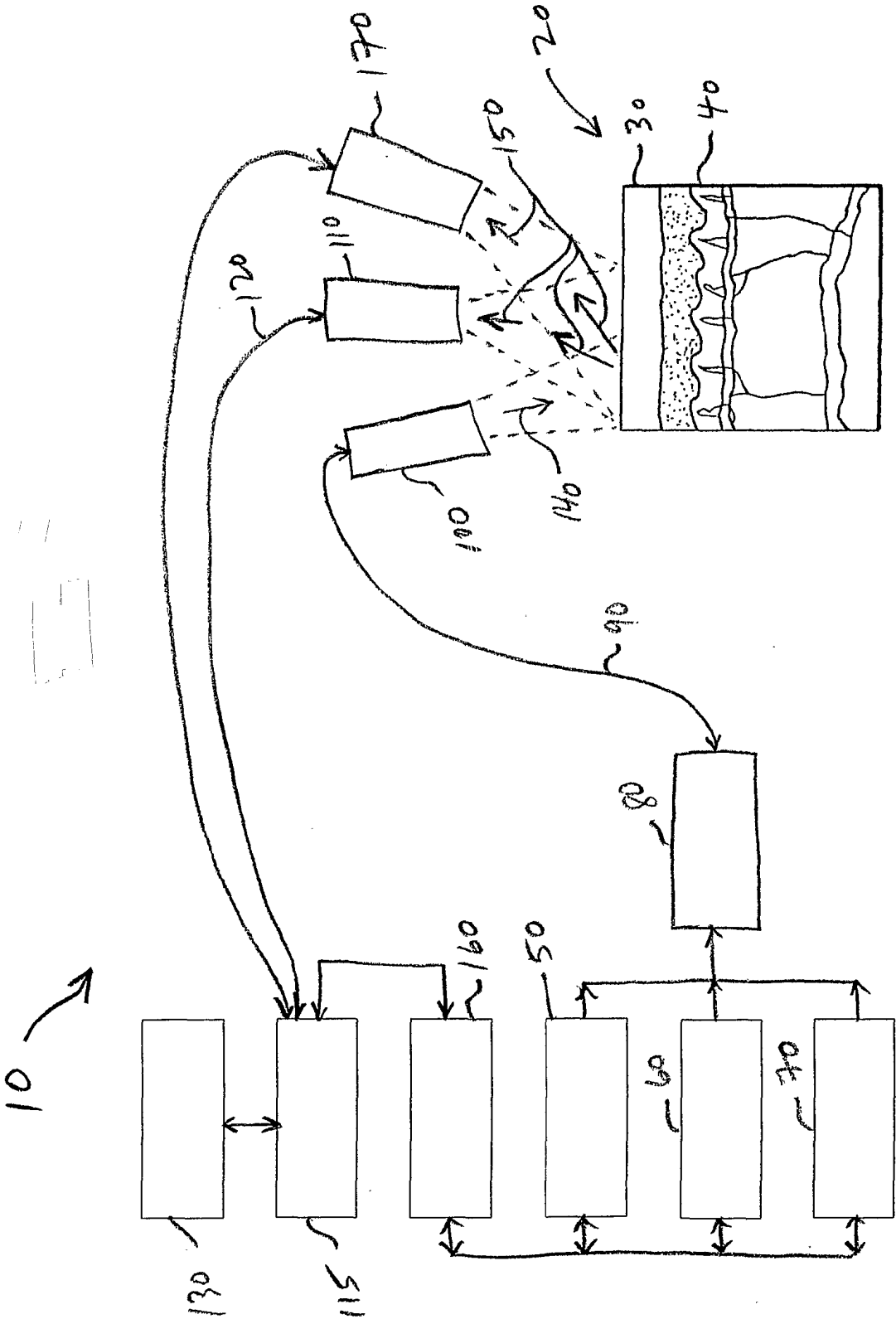


FIG. 1

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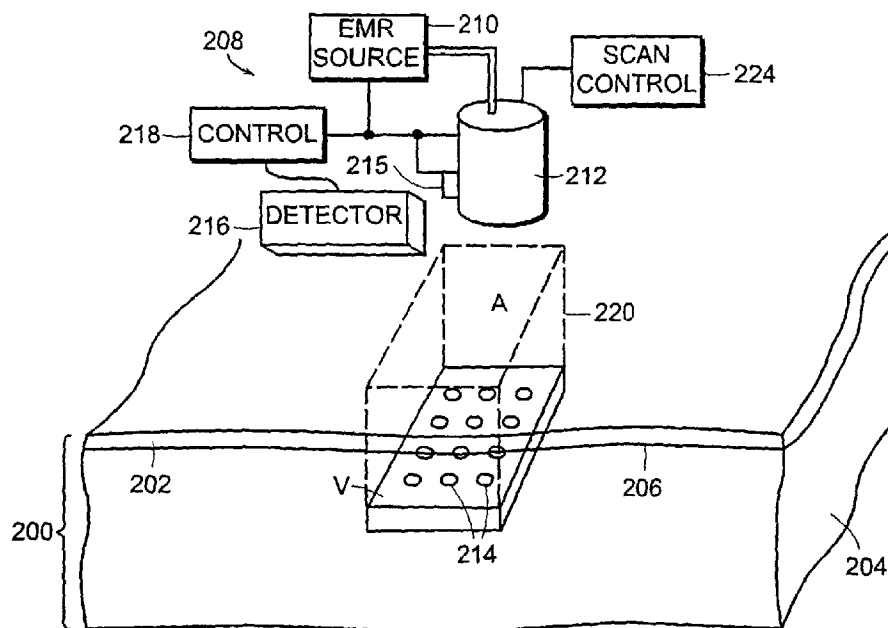
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[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR THERAPEUTIC EMR TREATMENT OF THE SKIN



(57) Abstract: A method and apparatus are provided for performing a therapeutic treatment on a patient's skin by concentrating applied radiation of at least one selected wavelength at a plurality of selected, three-dimensionally located, treatment portions, which treatment portions are within non-treatment portion. The ratio of treatment portions to the total volume may vary from 0.1 % to 90 %, but is preferably less than 50 %. Various techniques, including wavelength, may be utilized to control the depth to which radiation is concentrated and suitable optical systems may be provided to concentrate applied radiation in parallel or in series for selected combinations of one or more treatment portions.



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- 1 -

METHOD AND APPARATUS FOR THERAPEUTIC EMR TREATMENT OF THE SKIN

5

FIELD OF THE INVENTION

This invention relates to methods and apparatus for using electromagnetic radiation (EMR) for various therapeutic treatments and more particularly to methods and apparatus for dermatological treatment by use of spatially confined and concentrated EMR to create areas of treatment or damage substantially surrounded by areas of sparing.

BACKGROUND OF THE INVENTION

Various forms of electromagnetic radiation, particularly optical radiation, both coherent and non-coherent, have been utilized for many years for a variety of medical treatments, and in particular for dermatology treatments. Such treatments include, but are by no means limited to, removal of unwanted hair, skin rejuvenation, removal of vascular lesions, acne treatment, treatment of cellulite, pigmented lesions and psoriasis, tattoo removal, treatment of skin and other cancers, etc. Most of these treatments have involved in one way or another the use of a process known as selective photothermolysis (See for example Anderson RR, Parrish J., Selective photothermolysis: Precise microsurgery by selective absorption of the pulsed radiation. Science 1983; 220: 524-526), this process involving irradiating a target area to be treated with radiation at a wavelength preferentially absorbed by a chromophore, either a natural chromophore or artificially introduced chromophore, in the target area, the heating of the chromophore either directly or indirectly effecting the desired treatment.

While these techniques are useful for many of the indicated applications, these techniques have a number of significant limitations. First, treatments which are performed over a relatively large area, such as skin rejuvenation and hair removal, particularly skin rejuvenation, can cause varying degrees of skin damage over a substantial treatment area. In particular, such treatments can sometimes result in a detachment of skin layers. These relatively large areas of skin damage can frequently take several weeks or more to heal, and

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follow-up treatments can normally not be performed during this period. It would be preferable if these procedures could be performed in a manner which would result in smaller, spaced areas of damage which heal more quickly, this enhancing both patient comfort and the ability to more quickly perform follow-up treatments. Further, many treatments, such as for example hair removal and wrinkle removal, only require that the treatment be performed in small portions or regions of a much larger treatment area; however, current techniques of treatment generally require that the treatment be performed over the entire treatment area rather than in only the selected regions of the treatment area requiring treatment.

Another potential problem is the need for a chromophore in the target area which selectively absorbs the applied radiation to generate the heat required for treatment. First, to the extent the regions above the treatment area contain a chromophore which preferentially absorbs or otherwise absorbs the applied radiation, such chromophores are also heated, and care must be exercised in any treatment to assure that such heating does not result in epidermal or dermal damage. Various forms of cooling of such overlying regions, sometimes aggressive cooling, are frequently required to permit such treatments to be performed without damage to the overlying skin. For example, for hair removal or other treatments where melanin is targeted, heating of melanin in the epidermis, particularly at the dermis-epidermis (DE) junction, is a problem. Where the chromophore being targeted is water, substantially all tissue in the treatment area and thereabove will be absorbing the radiation and will be heated, making controlled treatment of a selected body component difficult, and increasing the likelihood of unwanted peripheral damaged.

Another problem with selective photothermolysis is that the wavelength selected for the radiation is generally dictated by the absorption characteristics of the chromophore utilized. However, such wavelengths may not be optimal for other purposes. For example, skin is a scattering medium, but such scattering is far more pronounced at some wavelengths than at others. Unfortunately, wavelengths preferentially absorbed by for example melanin, a frequently used chromophore, are also wavelengths at which substantial scattering occurs. This is also true for the wavelengths typically utilized for treating vascular lesions. Photon absorption in skin also varies over the optical wavelength band, wavelengths dictated by

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selective photothermolysis frequently being wavelengths at which skin is highly absorbent. The fact that wavelengths typically utilized for selective photothermolysis are highly scattered and/or highly absorbed limits the ability to selectively target body components, and in particular, limits the depths at which treatments can be effectively and efficiently performed. Further, the fact that much of the energy applied to a target region is either scattered and does not reach the body component undergoing treatment, or is absorbed in overlying or surrounding tissue to cause undesired and potentially dangerous heating of such tissue, results in optical dermatology treatments being relatively inefficient. This low efficiency for such treatments means that larger and more powerful EMR sources are required in order to achieve a desired therapeutic result and that additional cost and energy must be utilized to mitigate the effects of this undesired heating by surface cooling or other suitable techniques. Heat management for the more powerful EMR source is also a problem, generally requiring expensive and bulky water circulation or other heat management mechanisms. Further, since chromophore concentration in a target (for example melanin in the hair) varies significantly from target to target and from patient to patient, it is difficult to determine optimum, or even proper parameters for effective treatment of a given target using selective photothermolysis. High absorption by certain types of skin, for example dark skinned individuals or people with very tanned skin, often makes certain treatments difficult, or even impossible, to safely perform. A technique which permitted all types and pigmentations of skin to be safely treated, preferably with little or no pain, and preferably using substantially the same parameters, is therefore desirable.

Still another problem with existing treatment is that the amount of energy which can be applied to the treatment area, even where damage to the epidermis, skin scarring or other damage is not an issue, is frequently limited by pain experienced by the patient. Ideally, EMR dermatology procedures, which are typically for cosmetic purposes, should be painless or substantially painless. While if the procedure is being performed by a physician, pain may be controlled by the use of a local anesthetic, or even by putting the patient to sleep, there are risks in the use of any anesthetic, and the use of needles to administer a local anesthetic is undesirable for cosmetic procedures. It would therefore be preferable if patient pain could be substantially reduced or eliminated without the need for such procedures,

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while still permitting sufficient radiation to be applied to achieve a desired therapeutic result.

There are also occasions where microsurgery is required or desired on a patient's skin, particularly near the skin surface, where the area to be treated is of a size in the micron range, for example 10 microns, a size which cannot be treated with a scalpel. Existing EMR devices for performing microsurgery are also not adapted for performing surgery on such small targets. A need therefore exists for improved techniques for performing such fine microsurgery.

Further, while EMR techniques are available for treating some of the conditions indicated above, such techniques do not currently exist for treating scars, including acne scars, chicken pox scars and the like, for bumps in the skin resulting from scar tissue, for stretch marks, for treating certain parasites, etc.. An effective technique for treating such conditions is therefore needed.

Still another problem is in the removal of tattoos or pigmented lesions, particularly close to the skin surface, where existing techniques frequently result in blistering and other skin problems. An improved technique which would permit the fading of such tattoos or pigmented lesions and/or the ultimate removal thereof in a gentle enough manner so as to not cause damage to the patient's skin or significant patient discomfort is also desirable. Similar techniques for treating various skin blemishes are also desirable.

Finally, while techniques currently exist which are relatively effective in treating large vascular lesions, such techniques are not as efficient in treating spider veins and other small veins. Similar inefficiencies exist where radiation is applied over a relatively large area of a patient's skin where treatment is required in only relatively small portions of such area.

A need therefore exists for an improved method and apparatus for EMR therapeutic treatments, and in particular for optical dermatology treatments, which permit more selective treatment in target areas, and which do not rely on selective photothermolysis so that the wavelengths utilized may be selected so as to be more efficient for delivery of radiation to a desired target volume at a selected depth, and in particular to selected portions of such a

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target volume, which portions are preferably surrounded by portions which are not treated, and so that proper parameters for treating a given target may be more easily determined.

SUMMARY OF THE INVENTION

In accordance with the above, this invention provides a method and apparatus for performing a treatment on a volume located at area and depth coordinants of a patient's skin, the method involving providing a radiation source and applying radiation from the source to an optical system which concentrates the radiation to at least one depth within the depth coordinants of the volume and to selected areas within the area coordinants of the volume, the at least one depth and the selected areas defining three-dimensional treatment portions in the volume within untreated portions of the volume. The apparatus has the radiation source and an optical system to which radiation from the source is applied, the optical system concentrating the radiation to at least one depth in the volume and to selected areas of the volume, the at least one depth and the areas defining the three-dimensional treatment portions in the volume within untreated portions of the volume. For both the method and apparatus, the ratio of the treatment portions to the volume may be between 0.1% and 90%, but is preferably between 10% and 50%, and more preferably between 10% and 30%. In each instance, the treatment portions may be cylinders, spheres, ellipsoids, solid rectangles or planes of at least one selected size and thickness. The treatment portions may also be spaced lines of a selected length and thickness. The optical system may either apply radiation to all the treatment portions substantially simultaneously or the optical system may apply radiation to at least selected treatment portions sequentially.

The patient's skin over at least one treatment portion may also be pre-cooled to a selected temperature for a selected duration, the selected temperature and duration for pre-cooling preferably being sufficient to cool the skin to at least a selected temperature below normal body temperature to at least the at least one depth for the treatment portions. For selected embodiments, the skin is cooled to at least the selected temperature to a depth below the at least one depth for the treatment portions so that the at least one treatment portion is substantially surrounded by cooled skin. The cooling may continue during the applying of radiation, and for this embodiment, the duration of the applying of radiation may be greater than the thermal relaxation time of the treatment portions. The wavelength for the

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radiation source is preferably selected so as not to be either highly absorbed or scattered in the patient's skin above the volume on which treatment is to be performed. For deeper depth coordinants, the optical system focuses to a selected depth below the at least one depth of the treatment portions in order to achieve concentration at the desired depth coordinant in the patient's skin. A selected condition in the volume on which treatment is being performed and/or the patient's skin above this volume may be detected, the results of the detecting being utilized during the applying of radiation to control the treatment portions to which radiation is concentrated.

The applied radiation preferably has an output wavelength which is at least in part a function of the at least one depth of the treatment portions. More specifically, the wavelength of the applied radiation may be selected as a function of the applied radiation as follows: depth = .05 to .2 mm, wavelength = 400 – 1880 nm & 2050-2350 nm, with 800-1850 nm & 2100-2300 nm preferred; depth = .2 to .3mm, wavelength = 500-1880nm & 2050-2350nm, with 800-1850 nm & 2150-2300 nm preferred; depth = .3 to .5 mm, wavelength = 600-1380 nm & 1520-1850 nm & 2150-2260 nm, with 900-1300 nm & 1550-1820 nm & 2150-2250 nm preferred; depth = .5 to 1.0 mm, wavelength = 600-1370 nm & 1600-1820 nm, with 900-1250 nm & 1650-1750 nm preferred; depth = 1.0 to 2.0 mm, wavelength = 670-1350 nm & 1650-1780 nm, with 900-1230 nm preferred; depth = 2.0 to 5.0 mm, wavelength = 800-1300 nm, with 1050-1220 nm preferred.

The method and apparatus may also be utilized to treat a variety of medical conditions. Where a vascular lesion at a selected depth is being treated, treatment parameters, including the optical system and the wavelength of the applied radiation are selected so that the at least one depth of the treatment portions are at the depth of the vessel being treated. Similarly, where the treatment is skin remodulation by treatment of collagen or hair removal, treatment parameters, including the optical system and the radiation wavelength are selected so that the at least one depth is the depth of interdermal collagen and the depth of at least one of the bulge and matrix of the hair follicle, respectively. The teachings of this invention may also be used to treat acne, to target and destroy pockets of fat, to treat cellulite, for tattoo removal, for treating pigmented lesions, for treating

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hypotrophic and other scars and other skin blemishes, and for treating various other conditions in the skin.

The optical system utilized in practicing this invention may include an array of optical elements to at least a plurality of which radiation from the source is simultaneously applied, each of the optical elements concentrating the radiation to a selected portion of the volume. Each of the optical elements may for example focus or concentrate to a line of selected length and thickness, the lines for some of the elements being at a selected angle to the lines of other of the elements. The optical system may alternatively include apparatus for scanning radiation applied to optical concentrating components so as to successively focus radiation to N of the treatment portions at a time, where $N \geq 1$. The optical system may instead include adjustable depth optical focusing components, and a positioning mechanism for such optical focusing components which moves the components to focus at successive treatment portions. The apparatus may also include a mechanism which cools the part of the patient's skin at least over the selected area coordinants to a selected temperature, and controls which selectively operate the cooling mechanism to pre-cool this part of the patient's skin for a selected duration before application of radiation and/or during application of radiation. The cooling mechanism and the controls may pre-cool the skin to a temperature and for a duration sufficient to cool the part of the skin to at least a selected temperature below normal body temperature to the at least one depth of the treatment portions or may cool to a depth below the at least one depth of the treatment portions, the treatment portions in the latter case being substantially surrounded by cooled skin. The apparatus may also include a detector for at least one selected condition in the volume and/or in a part of the patient's skin above the volume and the optical system may operate in response to the detector to control the treatment portion of the volume to which radiation is concentrated.

The invention also includes a method and apparatus for performing a treatment on a volume located at an area and depth coordinant of a patient's skin which includes providing a radiation source and pre-cooling the patient's skin over at least part of the area coordinant of the volume to a selected temperature for a selected duration, the selected temperature and duration being sufficient to cool the skin to a depth below the depth coordinant of the

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volume; and applying radiation to an optical system which concentrates the radiation to at least one depth coordinant and to selected areas within the area coordinants to define treatment portions in the volume, the treatment portions being less than the total volume and each treatment portion being within untreated portions and being substantially surrounded by cooled skin. More specifically, a mechanism may be provided which cools the patient's skin over the area coordinant to the selected temperature and controls may be provided for selectively operating the cooling mechanism to pre-cool the skin for a selected duration before application of radiation and/or during application of radiation, the mechanism and controls cooling to a temperature and for a duration sufficient to cool the skin to at least a selected temperature below normal body temperature to at least a depth below the depth coordinant of the volume. The cooling of the patient's skin by the cooling mechanism may continue during the step of applying radiation and the duration of radiation application may be greater than the thermal relaxation time of each treatment portion.

Finally, the invention includes a method and apparatus for performing a therapeutic treatment on a patient's skin by concentrating applied radiation of at least one selected wavelength at a plurality of selected three-dimensionally located treatment portions, which treatment portions are within non-treatment portions.

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of various embodiments of the invention as illustrated in the accompanying drawings, the same or related reference numerals being used for common elements in the various figures.

IN THE DRAWINGS

Figs. 1-1B are top views of three optical systems involving arrays of optical elements suitable for use in delivering radiation in parallel to a plurality of target portions.

Figs. 2-3C are side views of various lens arrays suitable for delivering radiation in parallel to a plurality of target portions.

Figs. 4-4C are side views of Fresnel lens arrays suitable for delivering radiation in parallel to a plurality of target portions.

Figs. 5-5B are side views of holographic lens arrays suitable for use in delivering radiation in parallel to a plurality of target portions.

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Figs. 6-6A are side views of gradient lens arrays suitable for use in delivering radiation in parallel to a plurality of target portions.

Figs. 7-7B are top views of various matrix arrays of cylindrical lenses, some of which are suitable for providing a line focus for a plurality of target portions.

5 Figs. 8-8C are cross-sectional or side views of one layer of a matrix cylindrical lens system suitable for delivering radiation in parallel to a plurality of target portions.

Figs. 9-9B are a perspective view and cross-sectional side views, respectively, of a two layer cylindrical lens array suitable for delivering radiation in parallel to a plurality of target portions.

10 Figs. 10-13 are side views of various optical objective arrays suitable for use in concentrating radiation to one or more target portions.

Figs. 14-19 are side views of various deflector systems suitable for use with the arrays of Figs. 10-13 to move to successive target portions.

15 Figs. 20 and 21 are side views of two different variable focus optical system suitable for use in practicing the teachings of this invention.

Figs. 22A and 22B are semi-schematic perspective and side views respectively of a section of a patient's skin and of equipment positioned thereon for practicing the teachings of this invention.

DETAILED DESCRIPTION

20 Referring first to Figs. 22A and 22B, a portion of a patient's skin 200 is shown, which portion includes an epidermis 202 overlying a dermis 204, the junction of the epidermis and dermis being referred to as the dermis-epidermis (DE) junction 206. Also shown is a treatment volume V located at a depth d in the patient's skin and having an area A. Treatment volume V may contain one or more vascular lesions which are to be destroyed
25 or removed, may contain a plurality of hair follicles which are to be either permanently destroyed, or at least be damaged so as to result in temporary hair loss, or which are to be stimulated to cause hair growth, may contain in the area below the DE junction collagen which is to be restructured by various means, for example by being temporarily destroyed to stimulate regrowth, particularly for skin rejuvenation and wrinkle removal, may contain a
30 melanoma to be removed, a vascular lesion, pigmented lesion, port wine stain, psoriasis,

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scar, or other skin blemish or a tattoo to be removed, or some other bodily component on which optical dermatology procedures are performed .

Also shown is a system 208 for delivering optical radiation to volume V. System 208 includes an EMR source 210, which source may be a coherent light source, such as a solid-state laser, dye laser, diode laser, fiber laser or other coherent light source, or may be an incoherent light source, for example a flash lamp, halogen lamp, light bulb or other incoherent light source used to deliver optical radiation in dermatology procedures.

Acoustic, RF or other EMF sources may also be employed in suitable applications. The output from source 210 is applied to an optical system 212, which is preferably in the form of a deliver head in contact with the surface of the patient's skin as shown in Fig. 22B.

Where an acoustic, RF or other non-optical EMR source is used as source 210, system 212 would be a suitable system for concentrating or focusing such EMR, for example a phased array, and the term "optical system" should be interpreted, where appropriate, to include such system.

Various embodiments of an optical system 212 are discussed hereinafter and shown in the various figures. Generally, system 212 functions to receive radiation from source 210 and to focus/concentrate such radiation to a focused one or more beams 222 directed to a selected one or more treatment or target portions 214 of volume V, the focus being both to the depth d and spatially in the area A. The energy of the applied EMR is thus concentrated to deliver more energy to target portions 214. Depending on system parameters, portions 214 may be cylinders of selected diameter and thickness, spheres or ellipsoids, and for one embodiment may have a square or rectangular cross-section. The portions of each shape may extend through volume V or may be formed in a single layer or staggered layers thereof. Target portions 214 may also be (a) relatively narrow strips which may either extend through volume V, be formed in a single thin layer in volume V or be in staggered layers of the volume; or (b) may be one or more thin layers formed in volume V. As will be discussed in greater detail hereinafter, optical system 212 may focus to all or a selected subset of portions 214 simultaneously, may contain some type of optical or mechanical-optical scanner for moving radiation focused to depth d to successive portions 214, or may generate an output focused to depth d and be physically moved on the skin surface over

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volume V, either manually or by a suitable two-dimensional or three-dimensional (including depth) positioning mechanism, to direct radiation to desired successive portions 214. For the two later embodiments, the movement may be directly from portion to portion to be focused on or the movement may be in a standard pattern, for example a grid pattern, with the EMR source being fired only when over a desired portion 214.

A cooling element 215 is also included to cool the surface of skin 200 over treatment volume V. As shown in Fig. 22A and 22B, cooling element 215 acts on optical system 212 to cool the portion of this system in contact with the patient's skin, and thus the portion of the patient's skin in contact with such element. Cooling element 215 may for example be a thermoelectric element, or may be a system for passing water, preferably chilled water, a gas, preferably a chilled gas, and possibly even a cryogenic gas, over such portion of the optical system. Other techniques for cooling the surface of the patient's skin known in the art could also be used. Further, where optical system 212 is not in contact with the patient's skin, cryogenic spray cooling, gas flow or other non-contact cooling techniques may be utilized. A cooling gel on the skin surface might also be utilized, either in addition to or instead of, one of the cooling techniques indicated above.

System 208 also includes an optional detector 216, which may for example be a CCD camera or other suitable detector for a selected characteristic of the patient's skin. The output from detector 216 is applied to a control 218, which is typically a suitably programmed microprocessor, but may be special purpose hardware or a hybrid of hardware and software. Control 218 controls both the turning on and turning off of source 210 and may also control the power profile of the radiation. Control 218 is also applied to optical system 212 to for example control focus depth for the optical system and to control the portion or portions 214 to which radiation is being focused/concentrated at any given time, for example by controlling scanning by the optical system and/or the beam radiating therefrom. Finally, controls 218 are applied to cooling element 215 to control both the skin temperature above the volume V and the cooling duration, both for precooling and during an irradiation.

In accordance with the teachings of this invention, system 208 controls a variety of parameters of the applied radiation. Data in Tables 1-3 were found based on Monte-Carlo

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modeling of photon propagation in the skin using standard parameters of skin scattering and absorption for different wavelength. These parameters include, but are by no means limited to:

1. The shape of treatment portions 214. Each of these portions may be a thin disk as shown, may be an elongated cylinder which may for example extend from a first depth closer to DE junction 206 to a second deeper depth or, as will be discussed later in conjunction with various optical systems to be described, may be a line focus, each of the lines having a selected length, width and orientation and adjacent lines being spaced by a selected amount. The orientation of the lines for the portions 214 in a given application need not all be the same, and some of the lines may, for example, be at right angles to other lines (see for example Figs. 7A and 7B). Lines can be oriented around a treatment target for greater efficacy. For example the lines can be perpendicular to a vessel or parallel to a wrinkle. Portions 214 may also be spherical, ellipsoidal and at least for one embodiment, may be a solid square or rectangle of selected thickness. The shape of portion 214 is dictated by the combined parameters of the focused optical signal applied thereto, with the duration of application and to a lesser extent the wavelength of the signal being significant factors in determining the shape of the targeted portions. For example, it has been found that with a 1720 nm laser operating at roughly 0.5 J to 2 J and having a pulse duration of 0.5 to 2 ms, a generally cylindrically shaped portion 214 is obtained. Conversely, with a 1250 nm laser operating in the same energy range and having a pulse duration of .5 to 3 seconds, with an average of 1 second, generally spherically-shaped target portions are obtained. The parameters for obtaining a particular portion shape may be determined in a variety of ways, including empirically. By suitable control of wavelength, focusing, spot size at the surface and other parameters, the portions 214, regardless of shape, may extend through volume V, may be formed in a single thin layer of volume V or may be staggered so that, for example, adjacent portions 214 are in different thin layers of volume V. The pattern of the target portions in volume V may also vary with application. Further, target portions 214 may also be (a) relatively narrow stripes which may either extend through volume V, be formed in a single thin layer or be staggered in different thin layers, with for example adjacent stripes being in different layers; or (b) may be one or more thin layers formed in volume V. While

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all of the prior configurations for target portion 214 could be formed either serially or in parallel, the last configuration with multiple thin layers in the volume V would probably need to be formed serially. The geometry of portions 214 controls the thermal damage in the treatment portion. Since a sphere provides the greatest gradient, and is thus the most spatially confined, it provides the most localized biological damage, and may therefore be the preferred target shape for applications where this is desirable.

2. The size of the treatment portions 214. For a depth of approximately 1 mm into the patient's skin, the minimum diameter of a portion 214, or the minimum width of a line 214, is estimated to be approximately 100 microns; however, much larger portions, several mm's or more, are possible. For greater depths, the minimum sizes will be greater.

3. Center to center spacing between portions 214. The center to center spacing is determined by a number of factors, including the size of portions 214 and the treatment being performed. Generally, it is desired that the spacing between adjacent portions 214 be sufficient to protect the patient's skin and facilitate healing of damage thereto, while still permitting the desired therapeutic effect to be achieved. In one application, as little as 4% of the volume V was damaged (i.e. a 4% fill factor); however, the damaged portions 214 would typically cover substantially more of treatment volume V. While theoretically, the ratio of the combined volume of treatment portions 214 to the volume V (also sometimes referred to as the fill factor) could be 0.1% to 90%, a preferred range for fill factor is 10% to 50% for some applications and 10% to 30% for most applications. It is important that there be at least some area of sparing around each of the islands or areas of treatment/damage 214 and that this area of sparing be sufficient to permit the skin to recover, such recovery being facilitated by melanosome migration..

4. The depth d for the volume V. While it may be difficult to achieve a small focal spot 214 at a depth much below 1 mm in a scattering medium such as skin, focussing at depths of up to 4 mm, and perhaps even more, may be possible so long as a tight focus is not required and a larger portion size 214, perhaps several millimeters, is acceptable.

5. Focus Depth. While as may be seen from Table 1, depth d for volume V and the focal depth of optical system 212 are substantially the same when focussing to shallow depths, it is generally necessary in a scattering medium such as skin to focus to a greater

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depth, sometimes a substantially greater depth, in order to achieve a focus at a deeper depth d. The reason for this is that scattering prevents a tight focus from being achieved and results in the minimum spot size, and thus maximum energy concentration, for the focused beam being at a depth substantially above that at which the beam is focussed. The focus
5 depth can be selected to achieve a minimum spot size at the desired depth d based on the known characteristics of the skin.

6. Wavelength. Both scattering and absorption are wavelength dependent. Therefore, while for shallow depths a fairly wide band of wavelengths can be utilized while still achieving a focused beam, the deeper the focus depth, the more scattering and
10 absorption become factors, and the narrower the band of wavelengths available at which a reasonable focus can be achieved. Table 1 indicates preferred wavelength bands for various depths, although acceptable, but less than optimal, results may be possible outside these bands.

7. Pulse Width. Normally the pulse width of the applied radiation should be
15 less than the thermal relaxation time (TRT) of each of the targeted portions 214, since a longer duration will result in heat migrating beyond the boundaries of these portions. Since the portions 214 will generally be relatively small, pulse durations will also be relatively short as indicated in Table 1. However, as depth increases, and the spot sizes thus also increase, maximum pulse width or duration also increase. Again, the values given in Table
20 1 are maximum values for a given spot size and shorter pulses may be used. Generally, thermal diffusion theory indicates that pulse width τ for a spherical island should be $\tau < 500 D^2/24$ and the pulse width for a cylindrical island with a diameter D is $\tau < 50 D^2/16$. Further, the pulsewidths can sometimes be longer than the thermal relaxation time of the target portion 214 if density of the targets is not too high, so that the combined heat from the
25 target areas at any point outside these area is well below the damage threshold for tissue at such point. Also, as will be discussed later, with a suitable cooling regimen, the above limitation may not apply, and pulse durations in excess of the thermal relaxation time for a damage portion 214, sometimes substantially in excess of TRT, may be utilized.

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8. Power. The required power from the radiation source depends on the desired therapeutic effect, increasing with increasing depth and cooling and with decreasing absorption due to wavelength. The power also decreases with increasing pulse width.

9. Cooling. Typically cooler 215 is activated before source 210 to precool the patient's skin to a selected temperature below normal skin temperature, for example 0 to 10°C, to a depth of at least DE junction 206, and preferably to depth d to protect the entire skin region 220 above volume V. However, in accordance with the teachings of this invention, if precooling extends for a period sufficient for the patient's skin to be cooled to a depth below the volume V, and in particular if cooling continues after the application of radiation begins, then heating will occur only in the radiated portions 214, each of which portions will be surrounded by cooled skin. Therefore, even if the duration of the applied radiation exceeds TRT for portions 214, heat from these portions will be contained and thermal damage will not occur beyond these portions. Further, while nerves may be stimulated in portions 214, the cooling of these nerves outside of portions 214 will, in addition to permitting tight control of damage volume, also block pain signals from being transmitted to the brain, thus permitting treatments to be effected with greater patient comfort, and in particular permitting radiation doses to be applied to effect a desired treatment which might not otherwise be possible because of the resulting pain experienced by the patient. This cooling regimen is an important feature of the applicants invention.

10. Numerical Aperture. Numerical aperture is a function of the angle θ for the focused radiation beam 222 from optical device 212. It is preferable that this number, and thus the angle θ , be as large as possible so that the energy at portions 214 in volume V where radiation is concentrated is substantially greater than that at other points in volume V (and in region 220), thereby minimizing damage to tissue in region 220, and in portions of volume V other than portions 214, while still achieving the desired therapeutic effect in the portions 214 of volume V. Higher numerical aperture of the beam increases safety of epidermis, but it is limited by scattering and absorption of higher angle optical rays. As can be seen from Table 1, the possible numerical aperture decreases as the focus depth increases.

Thus, by judicious selection of the various parameters indicated above and others, one or more focused radiation beams 222 may be achieved to create islands of

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treatment/damage 214 in a treatment volume V at a selected depth d in the patient's skin. Preferred ranges of parameters for achieving these objectives at various depths are provided in Table 1. Table 2 and Table 3 illustrate ranges of parameters at various depths for short pulses (i.e., pulses of less than 10 ms for superficial small targets and less than 100 ms for deeper depths) and for long pulses respectively. The values in Table 2 assume that deep cooling through volume V as described above is not being provided so that the pulse duration is limited by the thermal relaxation time of damage portions 214. Thus, at shorter depths, where smaller spot or focus areas can be achieved, for example a spot having a diameter of 50 μm , as assumed in Table 2, pulse widths of less than 10 ms are required and other parameters are selected accordingly. Conversely, for deeper depths, tight focus cannot be achieved because of scattering, resulting in a significantly larger diameter for damage portions 214, and thus a larger thermal relaxation time for these portions. Therefore, substantially longer pulse widths can be provided, permitting required energy to achieve the therapeutic effect to be provided over a longer time interval. This facilitates removal of heat from region 220, and in particular from the epidermal portion 202 thereof and from DE junction 206. It also permits a lower peak power source 210 to be utilized. From Table 2, 3 it is also noted that the focus depth is indicated as greater than the depth d of the damage portions 214. The reasons for this have been discussed above.

While controls 218 can be preprogrammed to focus on selected portions 214 in target volume V, another option is to use feedback, either mechanically obtained by use of detector 216, or obtained by an operator, generally optically, but possibly using other of the operator senses such as touch or hearing, to control the portions 214 in volume V which are focused on. Assuming, for example, that detector 216 is a CCD imaging device, the location of hair follicles, vascular lesions, or other targeted components in volume V can be located and focused beams 222 specifically directed to the locations of such components. Thus, assuming a hair removal treatment, detector 216 could locate each hair follicle at the surface above volume V, and then focus a beam 222 to each such follicle at a selected depth, for example, a depth of 1 mm where stem cells are located. The beam could also be focused to an extended depth along the follicle, for example, 0.7-3 mm to assure destruction of all elements within the follicle required for permanent or substantially permanent hair removal,

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for example, destruction of follicle stem cells, without substantially damaging dermal tissue surrounding the follicle or damage to the follicle matrix. This result is most easily achieved if the cooling technique discussed above is utilized, with cooling extending below the treatment volume V so that each follicle being treated is surrounded by cooled dermal tissue.

5 Feedback could also be used to track a blood vessel or other vascular structure being treated or to track a wrinkle or wrinkles to be treated by collagen restructuring. Further, while focused beams 222 can be automatically positioned in response to outputs from detector 216 by control 218, such feedback can also be achieved by the operator manually adjusting the position of optical system 212 to track and treat hair follicles, vascular
10 structures, wrinkles or the like.

More specifically, the scanner used could include three low power laser diodes, preferably of different colors, used for detection and one high power laser diode used for treatment. The scanner can, for example, be utilized both to detect the location of the blood vessel and the depth of the blood vessel. One of the three diodes used for detection may be
15 a high power diode which can be operated in either a detection or treatment mode and detection, in some instances, may be performed by only one or two diodes, which diode or diodes may be also used for treatment in some cases. A suitable scanner can be used to move the detectors and/or treatment diode over a selected pattern. However, while galvanic scanners have been used in the past, a contact scanner is required for this application, since
20 the desired focusing of the beam requires contact, something which is not possible with a galvanic scanner. Again, the scanner can be programmed to trace a particular pattern to locate targets, and may be programmed to follow a target once located, for example a vein, or the scan may be manually controlled. Where the scan is following a selected target, for example a blood vessel, irradiation may occur at selected points along the blood vessel. It is
25 generally necessary to coagulate a blood vessel at a selected one or more points along the vessel in order to stop blood flow therein and kill the vessel. It should not be necessary to irradiate the entire vessel in order to effect destruction thereof.

Where a scanner is being used, the area scanned can be projected on a screen, providing effective magnification, which facilitates either the selection of desired target
30 points in a programmed scan or the performance of a scan along a desired target such as a

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blood vessel. Multiple detectors, which may be filtered to provide different colors, can be utilized for detecting the depth of a target, for example the blood vessel, so that light can be focused to the appropriate depth for treatment. Thus, scanning can be in three dimensions. Since depth is to some extent controlled by wavelength, a fiber laser, the output wavelength
5 of which is programmable over a limited range, may be utilized to control skin depth both for detection and treatment. In each instance, the treatment may be effected solely by focusing radiation to a selected point, water at the point normally being what is heated, or by the effect of such focusing coupled with selective absorption by the desired target at the wavelength utilized. The chromophor, while typically water, could also be blood or
10 melanin. Further, when treating blood vessels, since there is no need for hemoglobin as a chromophore, the vessel can be compressed during treatment, for example by applying pressure to the vessel. This can permit denaturation and shrinkage of the vessel wall, which can result in a more permanent closure of the vessel and in the potential to permanently close larger vessels. The location and size of the islands of treatment/damage can be
15 adjusted for different size, type and location of vessel. Similarly, for hair removal, since melanin need not be targeted, there is no requirement for high melanin content in the hair shaft or follicle, facilitating the easier treatment of gray and blond hair.

For port wine stains, wavelength can be in a range of 0.9 to 1.85 μm for water absorption or 0.38 to 1.1 μm for hemoglobin absorption with a fill factor of 10% to 80%, and
20 preferably, 30% to 50%. The light source can be an arc lamp with filtering and masking.

The teachings of this invention are also particularly adapted for skin rejuvenation treatments by collagen regeneration. In such treatments, since collagen is not itself a chromophor, a chromophor such as water in the tissues or blood in the papillary dermis or below typically absorbs radiation and is heated to heat the adjacent collagen, causing
25 selective damage or destruction thereof which results in collagen regeneration. Perturbing blood vessels in the region can also result in the release of fibroblasts which trigger the generation of new collagen. While such treatments may be made only along the line of a wrinkle or other blemish to be treated, such treatment is typically performed over a relatively large area undergoing treatment. In accordance with the teachings of this
30 invention, such treatments can be more effectively performed by heating selective portions

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214, with perhaps a 30% to 50% fill factor, resulting in significant collagen regeneration with less trauma and pain to the patient. Such procedure may be performed over a relatively large area A or, utilizing techniques similar to those discussed above for blood vessels, may be performed by periodically firing a beam when over a wrinkle, the beam being traced in a
5 predetermined pattern and fired only when over selected points on the wrinkle, or being moved to track a wrinkle and periodically fired while thereover. Also, as for other treatments where the teachings of this invention are employed, healing occurs relatively quickly so that a subsequent treatment, to the extent required, might generally be performed within a few weeks of an initial treatment, and certainly in less than a month.

10 Typically, a bump in the skin occurs when collagen is heated, the bump resulting from contraction of the collagen. Thus, this technique can be used not only to remove wrinkles but also to remove other skin blemishes such as acne or chicken pox scars or other scars in the skin and may also be utilized for treating cellulite. While the bump may recede after approximately a month, the heating also increases the thickness-to-length ratio of the
15 collagen in the area, thus increasing the collagen thickness, resulting in much of the improvement from skin rejuvenation/blemish removal being reasonably permanent.

Other skin blemishes treatable by the teachings of this invention include stretch marks, which differ from wrinkles in that these marks are substantially flush with the surface, the collagen shrinkage and regeneration as a result of heating reducing these marks.
20 Hypotrophic scarring, the raised scars which occur after surgery or certain wounds, can also be treated by reducing blood flow to the vessels of the scar in much the same way that port wine stains are treated above.

In addition to hair removal, treatment of vascular lesions, and skin resurfacing, the teachings of this invention can also be used to target and destroy a sebaceous gland or
25 glands, for example to treat acne, to target and destroy pockets of subcutaneous fat, to treat cellulite and to do skin resurfacing on areas where such treatments cannot currently be performed, for example neck and hands, where the damage caused using standard skin resurfacing techniques does not normally heal. The treating of only small islands in such areas should leave sufficient undamaged skin structure for healing to occur. The teachings
30 of this invention may, as indicated above, also be utilized for tattoo removal, for treating

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pigmented lesions, for treating hypotrophic and other scars, stretch marks, acne and chicken pox scars and other skin blemishes and for treating various other conditions which may exist in the patient's body at depths of less than approximate 4 mm, for example, various skin cancers and possibly PFB. For skin tumors, a combination may be used of a feedback
5 system that localizes the position of the tumor and a robotic system that insures complete thermal destruction of the tumor. Psoriasis may be treated in substantially the same way with substantially the same parameters as for port wine stain. The teachings may also be used to treat intredermal parasites such as larva migrans, which can be detected and selectively killed using the teachings of the invention.

10 There are three general ways in which the invention may be utilized for tattoo removal. The first is by using a wavelength or wavelengths absorbed by the tattoo ink, preferably with short, high fluence pulses, to break up or destroy the ink in and between cells. The second technique involves destroying the cells containing the ink, targeting either the ink or water in the cells, causing the ink to be released and removed by the body's
15 lymphatic system. Here long pulses in the millisecond to second range, having low power and high energy, would typically be utilized. In a third technique, an ablation laser would be used to drill 1 to 2 mm spots into the tattoo, ablating or vaporizing both cells and tattoo ink in these areas. With a small fill factor, in for example the 10% to 80% range, and preferable the 10% to 30% range, such small damage spots heal well, permitting the tattoo to be
20 progressively lightened and ultimately removed for each of the three treatments. A randomized pattern on each treatment is also preferable to interference of the removal pattern.

A particular problem for which the teachings of this invention are particularly adapted is the treating of birthmarks or other pigmented lesions in the epidermis. Such
25 lesions are generally difficult to treat without blistering using conventional treatment. By using islands of damage with a fill factor of 1% to 50%, and preferably 10% to 30%, and with a spot size of 100 microns to ½ mm, it is possible to treat such lesions without scarring. Since the treatment in this case is so close to the surface, focusing is not necessary. A similar treatment, with similar fill factor could be used for treating port wine stains or
30 tattoos, but in either of these cases, focusing would be required since the treatment is at a

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greater depth. In all cases, a first treatment might result in only the lightening of the treated area. Once the treated portion has healed, which generally would occur in a few weeks to a month with an islands of damage treatment, one or more additional treatments can be performed to further lighten the treated area until the lesion, port wine stain, tattoo or the like is removed. In each instance, dead cells resulting from the treatment containing melanocytes, ink or the like, would be removed by the body, normally passing through the lymphatic system.

Thus, a technique has been provided (a) which permits various therapeutic treatments on a patient's body at depths up to approximately 4 mm, (b) which permits only islands of damage in three dimensions to occur, thereby facilitating healing (by permitting continued blood flow and cell proliferation between skin layers and islands of damage 214) and reducing patient discomfort, (c) which permits targeting of specific components for treatment without damage to surrounding parts of the patient's body, thereby more efficiently using the applied radiation while also reducing peripheral damage to the patient's body as the result of such treatment (d) which permits treatment of all skin types using substantially the same parameters for a given treatment, thereby simplifying treatment set-up and treatment safety, and (e) which permits the wavelength utilized for treatment to be optimally selected for the depth of treatment, rather than being restricted to a wavelength optimally absorbed by a targeted chromophore. In fact, while the wavelengths selected for the teachings of this invention normally have significant water absorption, one of the criteria in selecting wavelengths is that they are not, particularly for deeper depths, highly absorbed, even by water, so that the radiation can reach desired depths without losing substantial energy/photons to absorption. The concentration of photons/energy at target portions 214 increases energy at these portions more than enough to compensate for reduced absorption at the wavelength utilized. This invention thus provides an entirely new and novel technique for performing such treatments.

Figs. 1-21 illustrates various optical components suitable for use in optical system 212. In these figures Figs. 1-9B illustrate various systems for delivering radiation in parallel to a plurality of target portions 214. The arrays of these figures are typically fixed focus arrays for a particular depth d. This depth may be changed either by using a different array

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having a different focus depth, by selectively changing the position of the array relative to the surface of the patient's skin or to target volume V or by controlling the wavelength(s) of the radiation. Figs. 10-13 show various optical objective arrays which may be used in conjunction with the scanning or deflector systems of Figs. 14-19 to move to successive one or more focused portions 214 within target volume V. Finally, Figs. 20 and 21 show two different variable focus optical systems which may, for example, be moved mechanically or manually over the patient's skin to illuminate successive portions 214 thereon.

Referring to these figures in greater detail, Figs. 1, 1A and 1B show a focusing element 1 on a substrate 3, the focusing element having a border which is in a hexagonal pattern (Fig. 1), a square pattern (Fig. 1A), and a circular or elliptical pattern (Fig. 1B). Standard optical materials can be used for these elements. While the hexagonal and square patterns of Fig. 1 and Fig. 1A can completely fill the working area of the focusing element plate 4, this is not true for the element pattern of Fig. 1B. Radiation from source 210 would typically be applied simultaneously to all of the focusing elements 1; however, the radiation could also be applied sequentially to these elements by use of a suitable scanning mechanism, or could be scanned in one direction, illuminating/irradiating for example four of the elements at a time.

Figs. 2 and 2A are cross-sectional views of a microlens system fused in a refracting material 8, for example, porous glass. The refractive index for the material of lenses 5 must be greater than the refractive index of refracting material 8. In Fig. 2, beam 11 initially passes through planar surface 10 of refracting material 8 and is then refracted both by primary surface 6 and by secondary surface 7 of each microlens 5, resulting in the beam being focused to a focal point 12. The process is reversed in Fig. 2A, but the result is the same.

In Figs. 2B and 2C, the incident beam 11 is refracted by a primary lens surface 6 formed of the refracting material 8. Surfaces 6 and 7 for the various arrays can be either spherical or aspherical.

In Figs. 3 and 3A, the lens pieces 15 are mounted to a substrate and are in an immersion material 16. The refraction index of lens pieces 15 are greater than the refraction index of immersion material 16. Immersion material 16 can be in a gas (air), liquid (water,

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cryogen spray) or a suitable solid. Gas and liquid can be used for cooling of the skin. The immersion material is generally at the primary and secondary plane surfaces, 13 and 14, respectively. In Fig. 3A, the primary surface 6 and secondary surface 7 of each lens piece 15 allows higher quality focusing to be achieved. For Figs. 3B and 3C, the lens pieces 15 are fixed on a surface of a refracting material 8, the embodiment of Fig. 3C providing a deeper focus than that of Fig. 3B, or that of any of other arrays shown in Figs. 3A-3C for a given lens 15. The lens arrays shown in Figs. 3A-3C are a preferred lens arrays for practicing the teachings of this invention.

Figs. 4-4C show Fresnel lens surfaces 17 and 18 formed on a refracting material 8. Changing the profile of Fresnel lens surface 17 and 18, the relationship between the radius of center 17 and ring 18 of the Fresnel surface, makes it possible to achieve a desired quality of focusing. The arrays of Figs. 4B and 4C permit a higher quality focusing to be achieved and are other preferred arrays. Surfaces 17 and 18 can be either spherical or aspherical.

In Figs. 5 and 5A, the focusing of an incident beam 11 is achieved by forming a holographic lens 19 (i.e., a photographic hologram) on a surface of refracting material 8. Holographic lenses 19 may be formed on either of the surfaces of refracting material 8 as shown in Figs. 5 and 5A or on both surfaces. Fig. 5B shows that the holographic material 20 substituted for the refracting material 8 of Figs. 5 and 5A. The holographic lens is formed in the volume of material 20.

In Figs. 6 and 6A, the focusing elements are formed by gradient lenses 22 having primary plane surfaces 23 and secondary plane surfaces 24. As shown in Fig. 6A, such gradient lenses may be sandwiched between a pair of refracting material plates 8 which provide support, protection and possibly cooling for the lenses.

Figs. 7, 7A and 7B illustrate various matrix arrays of cylindrical lenses 25. The relation of the lengths 26 and diameters 27 of the cylindrical lenses 25 can vary as shown in the figures. The cylindrical lens 25 of Figs. 7A and 7B provide a line focus rather than a spot or circle focus as for the arrays previously shown.

Figs. 8-8C are cross-sectional views of one layer of a matrix cylindrical lens system. The incident beam 11 is refracted by cylindrical lenses 25 (Figs. 8 and 8A) or half cylinder lenses 29 (Figs. 8B and 8C) and focus to a line focus 28. In Figs. 8B and 8C, the cylindrical

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lenses 29 are in the immersion material 16. Primary working optical surface 30 and secondary optical working surface 31, which may be spherical or aspherical, allowing high quality focusing to be achieved. As shown in Figs. 7-8C the line focuses for adjacent lenses may be oriented in different directions, the orientations being at right angles to each other for certain of the lenses in these figures.

In Figs. 9, 9A and 9B, a matrix of focal spots is achieved by passing incident beam 11 through two layers of cylindrical lenses 32 and 35. Figs. 9A and 9B are cross-sections looking in two orthogonal directions at the array shown in Fig. 9. By changing the focal distance of primary layer lens 32, having a surface 33, and secondary lens 35, having a surface 36, it is possible to achieve a rectangular focal spot of a desired size. Primary layer lens 32 and secondary layer lens 35 are mounted in immersion material 16. Lenses 32 and 35 may be standard optical fibers or may be replaced by cylindrical lenses which may be spherical or aspherical. Surfaces 34 and 37 can be of optical quality to minimize edge losses.

Fig. 10 shows a one lens objective 43 with a beam splitter 38. The beam 11 incident on angle beam splitter 38 divides and then passes through the refracting surfaces 41 and 42 of lens 43 to focus at central point 39 and off-center point 40. Surfaces 41 and 42 can be spherical and/or aspherical. Plate 54 having optical planar surfaces 53 and 55 permits a fixed distance to be achieved between optical surface 55 and focusing points 39, 40. Angle beam splitter 38 can act as an optical grating that can split beam 11 into several beams and provide several focuses.

In Fig. 11, a two lens 43,46 objective provides higher quality focusing and numerical aperture as a result of optimal positioning of optical surfaces 41, 42 and 44. All of these surfaces can be spherical or aspherical. Optical surface 45 of lens 46 can be planar to increase numerical aperture and can be in contact with plate 54. Plate 54 can also be a cooling element as previously discussed.

Fig. 12 differs from the previous figures in providing a three lens objective, lenses 43, 46 and 49. Fig. 13 shows a four lens objective system, the optical surfaces 50 and 51 of lens 52 allowing an increased radius of treatment area (i.e., the distance between points 39 and 40).

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Figs. 14, 14A and 14B illustrate three optical systems which may be utilized as scanning front ends to the various objectives shown in Figs. 10-13. In these figures, the collimated initial beam 11 impinges on a scanning mirror 62 and is reflected by this mirror to surface 41 of the first lens 43 of the objective optics. Scanning mirror 62 is designed to move optical axis 63 over an angle f . Rotational displacement of a normal 64 of mirror 62 by an angle f causes the angle of beam 11 to be varied by an angle $2f$. The optical position of scanning mirror 62 is in the entrance pupil of the focusing objective. To better correlate between the diameter of scanning mirror 62 and the radius of the working surface (i.e., the distance between points 39 and 40) and to increase the focusing quality, a lens 58 may be inserted before scanning mirror 62 as shown in Fig. 14A. Optical surfaces 56 and 57 of lens 58 can be spherical or aspherical. For additional aberration control, a lens 61 may be inserted between lens 58 and mirror 62, the lens 61 having optical surfaces 59 and 60.

Figs. 15, 15A and 15B are similar to Figs. 14, 14A and 14B except that the light source is a point source or optical fiber 65 rather than collimated beam 11. Beam 66 from point source 65, for example the end of a fiber, is incident on scanning mirror 62 (Fig. 15) or on surface 57 of lens 58 (Figs. 15A, 15B).

Figs. 16 and 16A show a two mirror scanning system. In the simpler case shown in Fig. 16, scanning mirror 67 rotates over an angle f_2 and scanning mirror 62 rotates over an angle f_1 . Beam 63 is initially incident on mirror 67 and is reflected by mirror 67 to mirror 62, from which it is reflected to surface 41 of optical lens 43. In Fig. 16A, to increase the numerical aperture of the focusing beam, increase work area on the skin and decrease aberration between scanning mirrors 62 and 67, an objective lens 106 is inserted between the mirrors. While a simple one lens objective 106 is shown in this figure, more complex objectives may be employed. Objective lens 106 refracts the beam from the center of scanning mirror 67 to the center of scanning mirror 62.

In Fig. 17, scanning is performed by scanning lens 70 which is movable in direction s . When scanning lens 70 is moved to an off center position 73, optical surface 68 refracts a ray of light along optical axis 71 to direction 72.

In Fig. 18, scanning is performed by rotating lens 76 to, for example, position 77. Surface 74 is planar and surface 75 is selected so that it does not influence the direction of

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refracted optical axis 72. In Fig. 19, scanning is performed by the moving of point source or optical fiber 65 in direction s.

Figs. 20 and 21 show zoom lens objectives to move the island of damage to different depths. In Fig. 20, a first component is made up of a single lens 81 movable along the optical axis relative to a second component which is unmovable and consists of two lenses 84 and 87. Lens 84 is used to increase numerical aperture. To increase numerical aperture, range of back-focal distance and decrease focal spot size, optical surfaces 79, 80, 82, 83 and 85 can be aspherical. The relative position of the first and second components determines the depth of focal spot 12.

Fig. 21 shows zoom lens objectives with spherical optical surfaces. The first component is made up of a single lens 90 movable with respect to the second component along the optical axis. The second component, which is unmovable, consists of five lenses 93, 96, 99, 102, and 105. The radius of curvature of surfaces 88 and 89 are selected so as to compensate for aberrations of the unmovable second component. Again, the depth of focus may be controlled by controlling the distance between the first and second components. Either of the lens systems shown in Figs. 20 and 21 may be mounted so as to be movable either manually or under control of control 218 to selectively focus on desired portions 214 of target volume V or to non-selectively focus on portions of the target volume.

While the invention has been shown and described above with reference to a number of embodiments, and variations on these embodiments have been discussed, these embodiments are being presented primarily for purposes of illustration and the foregoing and other changes in form and detail may be made in these embodiments by one skilled in the art without departing from the spirit and scope of the invention which is defined only by the appended claims.

What is claimed is:

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CLAIMS

1. A method for performing a treatment on a volume located at area and depth coordinates of a patient's skin including:

providing a radiation source; and

5 applying radiation from said source to an optical system which concentrates said radiation to at least one depth within said depth coordinate and to selected areas within said area coordinates of said volume, said at least one depth and said selected areas defining three dimensional treatment portions in said volume within untreated portions of said volume.

10 2. A method as claimed in claim 1 wherein the ratio of said treatment portions to said volume is between 0.1% and 90%.

3. A method as claimed in claim 2 wherein said ratio is 10% to 50%.

4. A method as claimed in claim 2 wherein said ratio is 10% to 30%.

15 5. A method as claimed in claim 1 wherein said treatment portions are one of cylinders, spheres, ellipsoids, solid rectangles or planes of at least one selected size and thickness.

6. A method as claimed in claim 1 wherein said treatment portions are spaced lines of a selected length and thickness.

20 7. A method as claimed in claim 1 wherein said optical system applies said radiation to all said treatment portions substantially simultaneously.

8. A method as claimed in claim 1 wherein said optical system applies said radiation to at least selected said treatment portions sequentially.

9. A method as claimed in claim 1 including precooling the patient's skin over at least one treatment portion to a selected temperature for a selected duration.

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10. A method as claimed in claim 9 wherein said selected temperature and duration for said precooling step are sufficient to cool said skin to at least a selected temperature below normal body temperature to at least said at least one depth.

11. A method as claimed in claim 10 wherein said skin is cooled to at least said
5 selected temperature to a depth below said at least one depth, whereby said at least one treatment portion is substantially surrounded by cooled skin.

12. A method as claimed in claim 11 including continuing to cool the patient's skin during said applying step.

13. A method as claimed in claim 11 wherein the duration of said applying step
10 is greater than the thermal relaxation time of treatment portions.

14. A method as claimed in claim 1 wherein wavelength for said radiation source is selected so as not to be either highly absorbed or scattered in the patient's skin above said volume.

15. A method as claimed in claim 1 wherein, for deeper depth coordinates, said
15 optical system focuses to a selected depth below said at least one depth in order to achieve concentration at said depth coordinate in the patient's skin.

16. A method as claimed in claim 1 including detecting selected conditions in at least one of said volume and the patient's skin above said volume, and utilizing results of said detecting during said applying step to control the treatment portions to which said
20 radiation is concentrated.

17. A method for performing a treatment on a volume located at area and depth coordinates of a patient's skin including:
providing a radiation source;
precooling the patient's skin over at least part of said area coordinate to a
25 selected temperature for a selected duration, said selected temperature and duration being

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sufficient to cool said skin to a depth below said depth coordinate to a temperature below normal body temperature; and

applying said radiation to an optical system which concentrates said radiation to at least one depth coordinate and to selected areas within said area coordinates to define treatment portions in said volume, said treatment portions being less than said volume, each
5 said treatment portion being within untreated portions and being substantially surrounded by cooled skin.

18. A method as claimed in claim 17 including continuing to cool the patient's skin during said applying step.

10 19. A method as claimed in claim 17 wherein the duration of said applying step is greater than the thermal relaxation time of each treatment portion.

20. A method as claimed in claim 1 wherein said radiation source has an output the wavelength of which is at least in part a function of said at least one depth.

21. A method as claimed in claim 20 wherein the applied radiation has a
15 wavelength which is selected as a function of said at least one depth as follows: depth = .05 to .2 mm, wavelength = 400 – 1880 nm & 2050-2350 nm, with 800-1850 nm & 2100-2300 nm preferred; depth = .2 to .3mm, wavelength = 500-1880nm & 2050-2350nm, with 800-1850 nm & 2150-2300 nm preferred; depth = .3 to .5 mm, wavelength = 600-1380 nm & 1520-1850 nm & 2150-2260 nm, with 900-1300 nm & 1550-1820 nm & 2150-2250 nm
20 preferred; depth = .5 to 1.0 mm, wavelength = 600-1370 nm & 1600-1820 nm, with 900-1250 nm & 1650-1750 nm preferred; depth = 1.0 to 2.0 mm, wavelength = 670-1350 nm & 1650-1780 nm, with 900-1230 nm preferred; depth = 2.0 to 5.0 mm, wavelength = 800-1300 nm, with 1050-1220 nm preferred.

22. A method as claimed in claim 1 wherein a vascular lesion at a selected depth
25 is being treated, treatment parameters, including the optical system and the wavelength of the applied radiation, being selected so that said at least one depth is the depth of the vessel being treated.

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23. A method as claimed in claim 1 wherein the treatment is skin remodulation ,
by treatment of collagen, treatment parameters, including the optical system and the
wavelength of applied radiation, being selected so that said at least one depth is at the depth
of interdermal collagen.

5 24. A method as claimed in claim 1 wherein the treatment is hair removal, the
treatment parameters, including the optical system and the wavelength of the applied
radiation, being selected so that said at least one depth is at the depth at least one of the
bulge and matrix of each hair follicle.

10 25. A method as claimed in claim 1 wherein the treatment is removal of one of
tattoos and pigmented lesions, said treatment portions being within the tattoo/pigmented
lesion being treated, at least two treatments, each with a selected treatment portion pattern
being performed.

15 26. A method as claimed in claim 1 wherein the treatment acne by damage to
sebaceous glands, treatment of intradermal parasites, and treatment of various skin
blemishes.

27. Apparatus for performing a treatment on a volume located at area and depth
coordinates of a patient's skin including:
a radiation source; and
an optical system to which radiation from said source is applied, said optical
20 system concentrating said radiation to at least one depth in said volume and to selected areas
of said volume, said at least one depth and said areas defining three dimensional treatment
portions in said volume within untreated portions of said volume.

28. Apparatus as claimed in claim 27 wherein the ratio of said treatment portions
to said volume is between 0.1% and 90%.

25 29. Apparatus as claimed in claim 28 wherein said ratio is 10% to 50%.

30. Apparatus as claimed in claim 29 wherein said ratio is 10% to 30%.

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31. Apparatus as claimed in claim 27 wherein said selected portions of said volume are one of cylinders, spheres, ellipsoids, solid rectangles and planes of a selected size and thickness spaced by a selected distance.

5 32. Apparatus as claimed in claim 27 wherein said selected portions of said volume are spaced lines of a selected length and thickness.

33. Apparatus as claimed in claim 27 wherein said optical system includes an array of optical elements to at least a plurality of which radiation from said source is simultaneously applied, each said optical element concentrating said radiation to a selected treatment portion of said volume.

10 34. Apparatus as claimed in claim 33 wherein each of said optical elements focuses to a line of selected length and thickness, the lines for some of said elements being at a selected angle to the lines for other of said elements.

35. Apparatus as claimed in claim 27 wherein said optical system includes apparatus for scanning radiation applied to optical concentrating components so as to
15 successively focus said radiation to N of said treatment portions at a time, where $N \geq 1$.

36. Apparatus as claimed in claim 27 wherein said optical system includes adjustable depth optical focusing components, and a positioning mechanism for said optical focusing components which moves the component to focus at successive treatment portions.

20 37. Apparatus as claimed in claim 27 including a mechanism which cools the part of the patient's skin at least over said selected area coordinate to a selected temperature, and controls for selectively operating said mechanism to at least one of precool said part of the patient's skin for a selected duration before application of radiation and during application of radiation.

25 38. Apparatus as claimed in claim 36 wherein said mechanism and controls precool said skin to a temperature and for a duration sufficient to cool the part of the skin to

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at least a selected temperature below normal body temperature to at least said at least one depth.

39. Apparatus as claimed in claim 37 wherein said skin is cooled to at least said selected temperature to a depth below said at least one depth, whereby each said treatment
5 portion is substantially surrounded by cooled skin.

40. Apparatus as claimed in claim 27 wherein said source generates radiation at a wavelength which is neither highly absorbent nor highly scattering in at least the parts of the patient's skin above said volume.

41. Apparatus as claimed in claim 27 wherein, for deeper depth coordinates, said
10 optical system concentrates to a selected depth below said at least one depth in order to achieve concentration at said depth in the patient's skin.

42. Apparatus as claimed in claim 27 including a detector for at least one selected condition in at least one of said volume and a part of the patient's skin above said volume, said optical system operating in response to said detector to control the treatment portions of
15 said volume to which said radiation is concentrated.

43. Apparatus for performing a treatment on a volume located at area and depth coordinates of a patient's skin including:

- a radiation source;
- a mechanism which cools the patient's skin over said area coordinate to a
20 selected temperature;
- controls for selectively operating said mechanism to at least one of precool said skin for a selected duration before application of radiation and during application of radiation, said mechanism and controls cooling to a temperature and for a duration sufficient to cool said skin to at least a selected temperature below normal body temperature
25 to at least a depth below said depth coordinate; and
- an optical system to which radiation from said source is selectively applied, said optical system concentrating said radiation to a depth in said volume and to selected

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areas of said volume to define treatment portions, said treatment portions being less than said total volume, each said portion being substantially surrounded by untreated and cooled skin.

44. Apparatus as claimed in claim 43 wherein said radiation is applied to said
5 optical system for a duration which is greater than thermal relaxation time of each portion.

45. A method for performing a therapeutic treatment on a patient's skin by concentrating applied radiation of selected wavelength at a plurality of selected, three-dimensionally located, treatment portions, which treatment portions are within non-treatment portions.

10 46. Apparatus for performing a therapeutic treatment on a patient's skin by concentrating applied radiation of selected wavelength at a plurality of selected, three-dimensionally located, treatment portions, which treatment portions are within non-treatment portions.

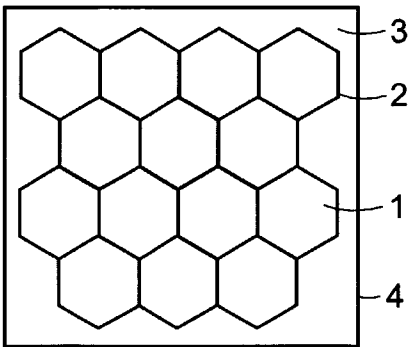


FIG. 1

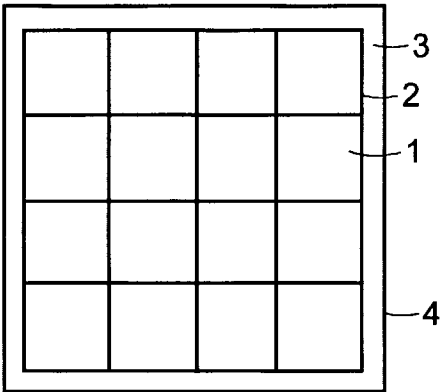


FIG. 1A

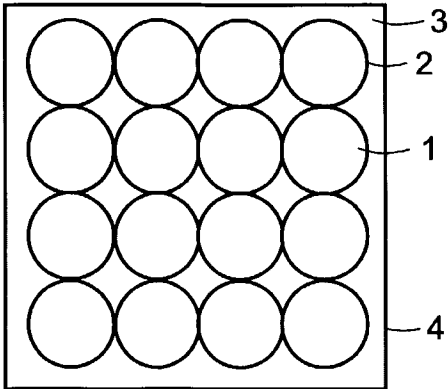


FIG. 1B

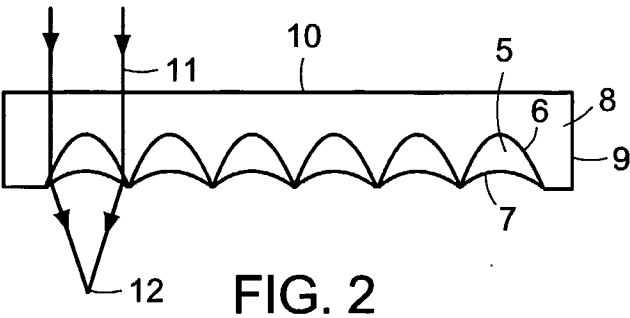


FIG. 2

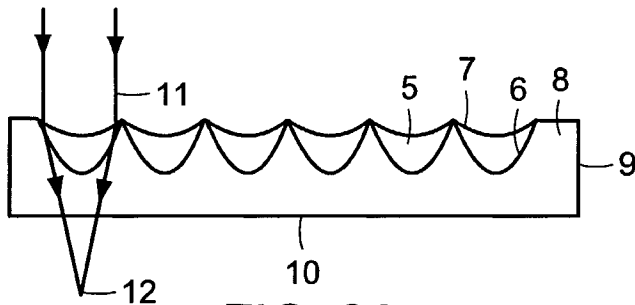


FIG. 2A

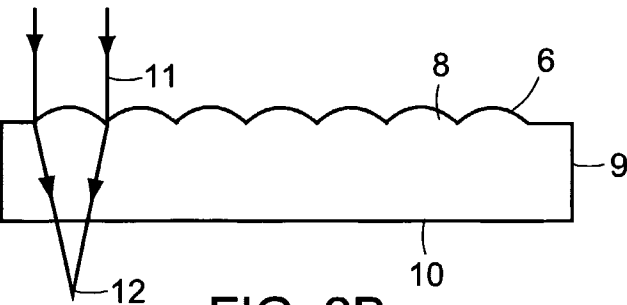


FIG. 2B

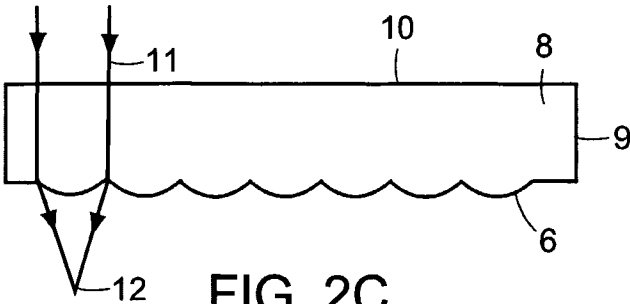
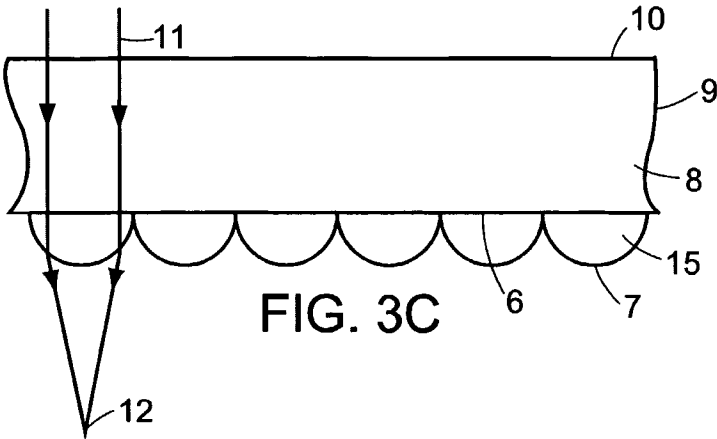
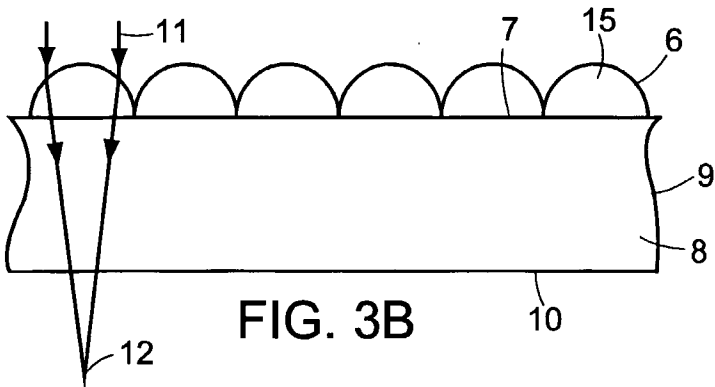
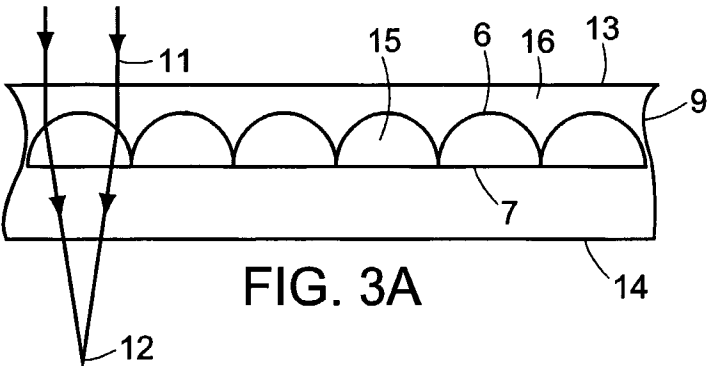
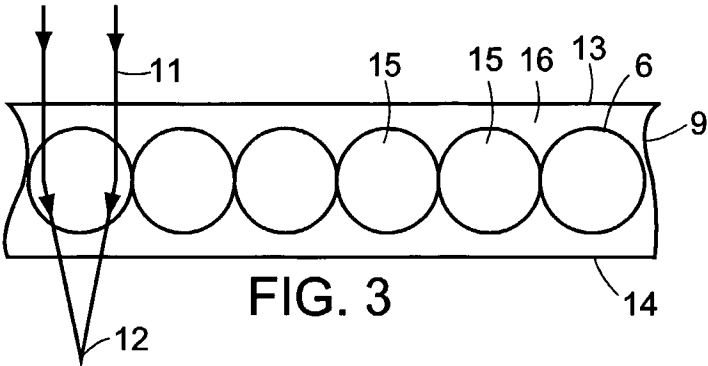


FIG. 2C



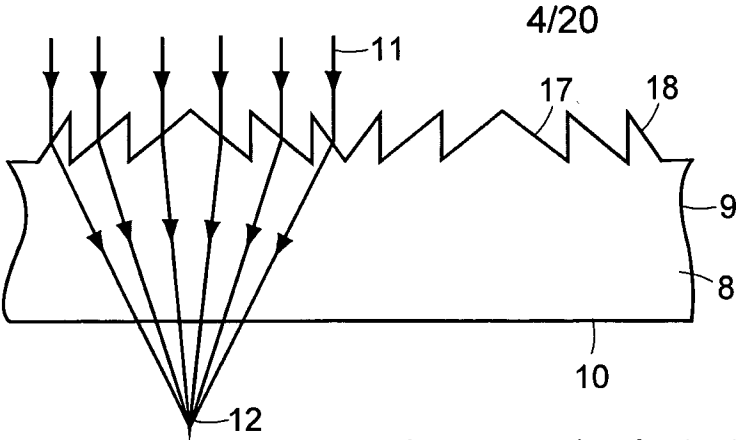


FIG. 4

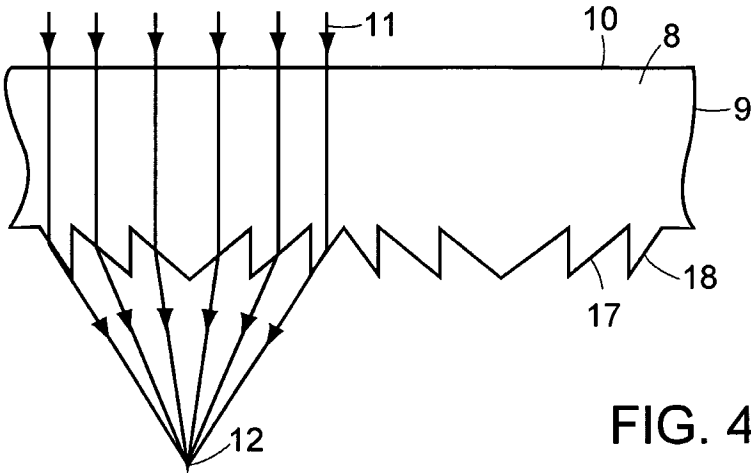


FIG. 4A

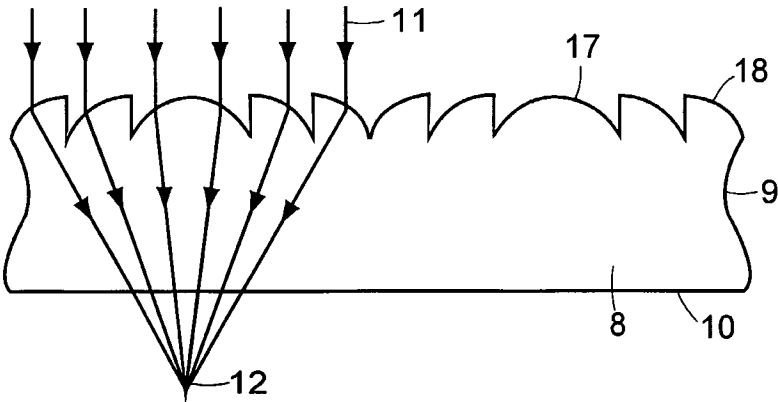


FIG. 4B

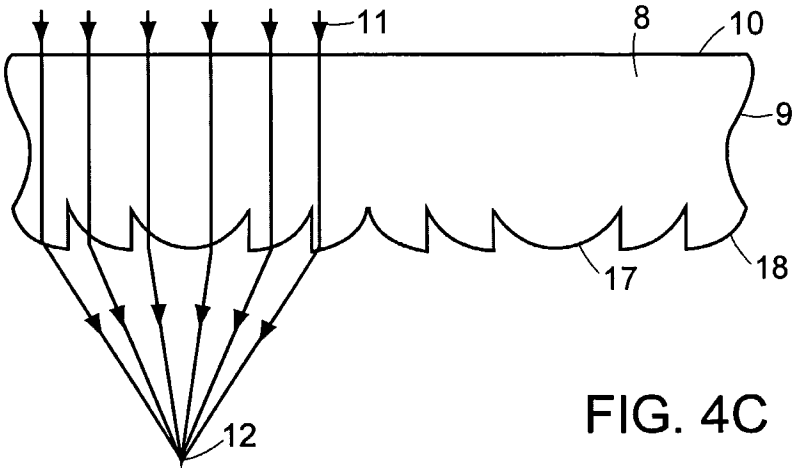
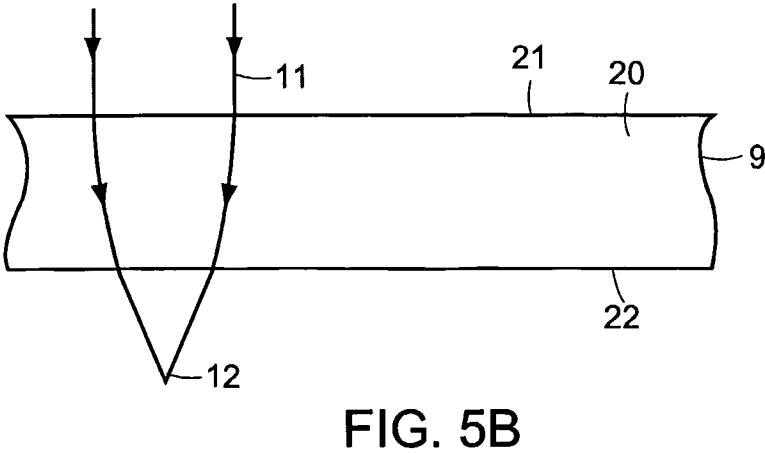
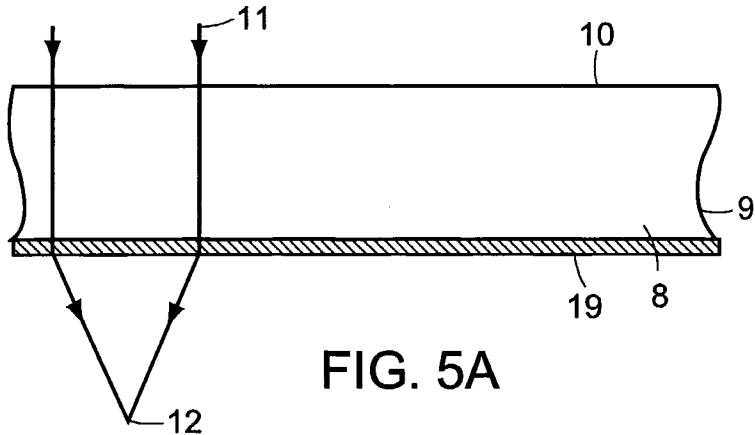
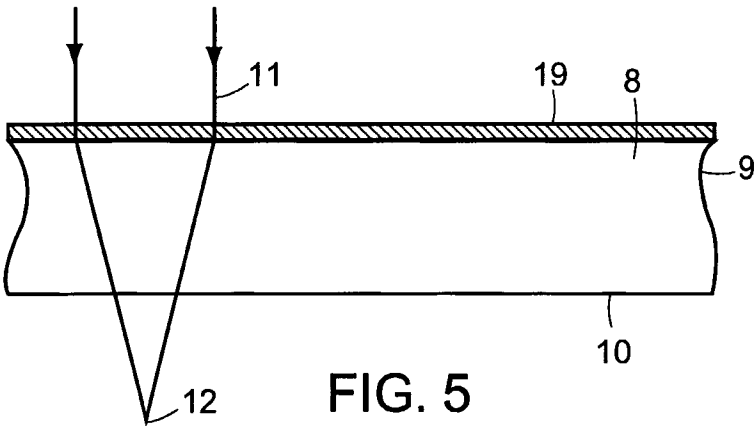


FIG. 4C



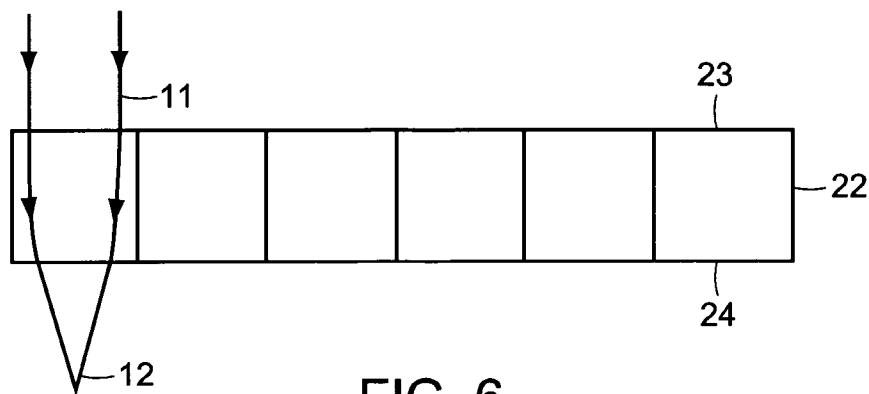


FIG. 6

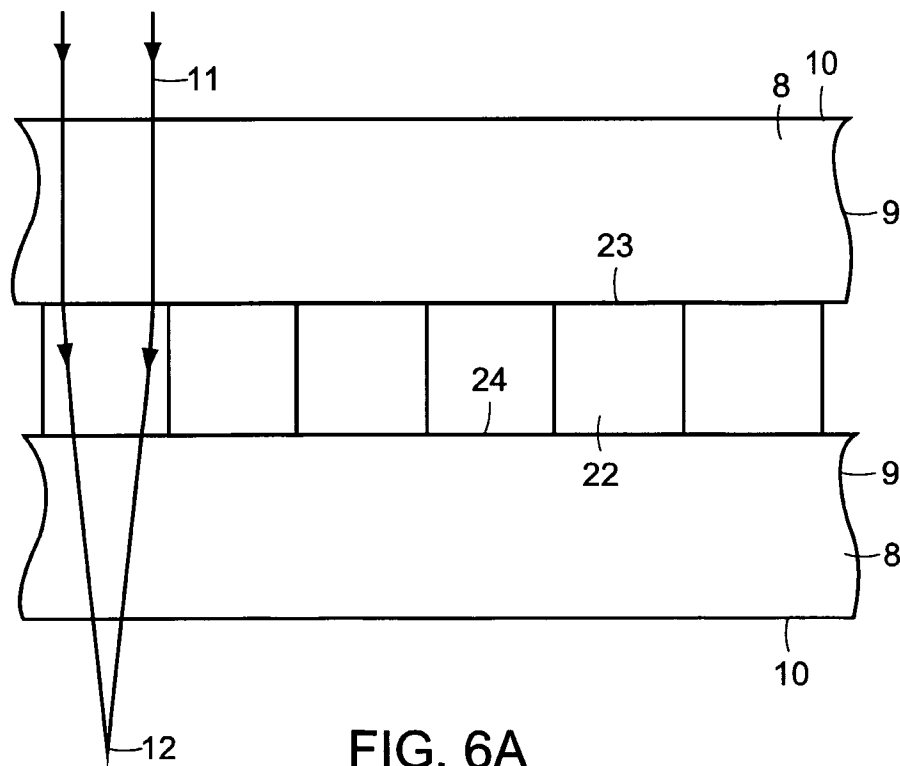


FIG. 6A

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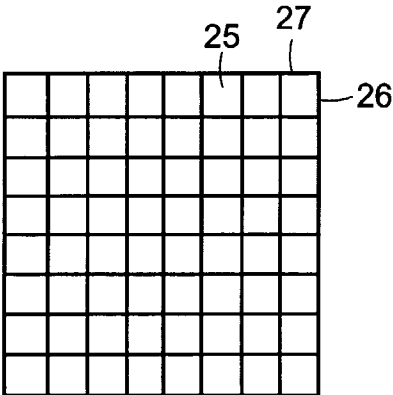


FIG. 7

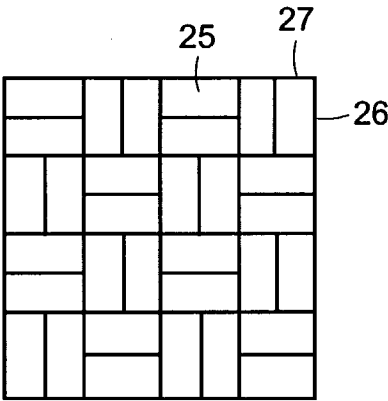


FIG. 7A

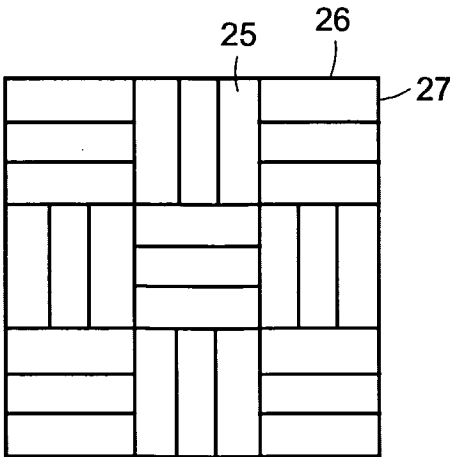


FIG. 7B

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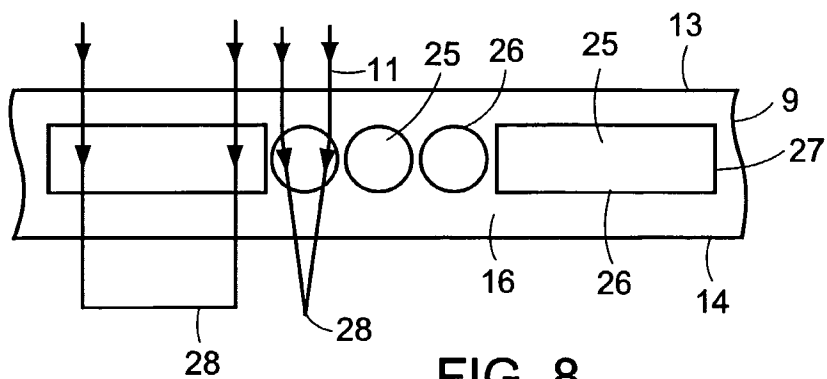


FIG. 8

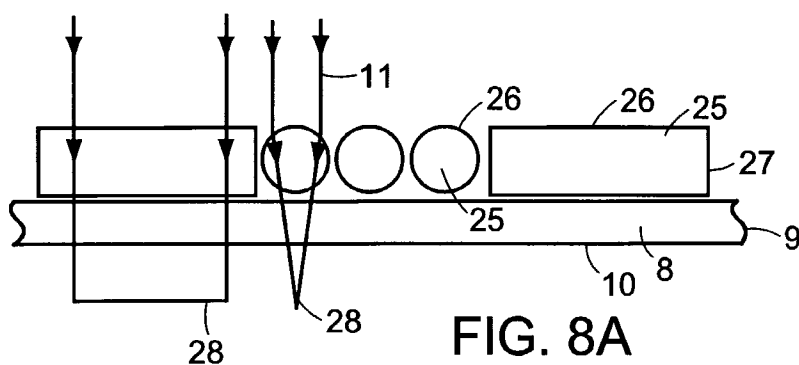


FIG. 8A

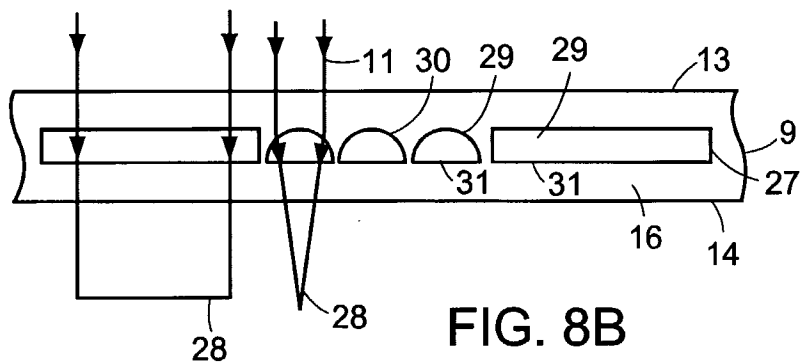


FIG. 8B

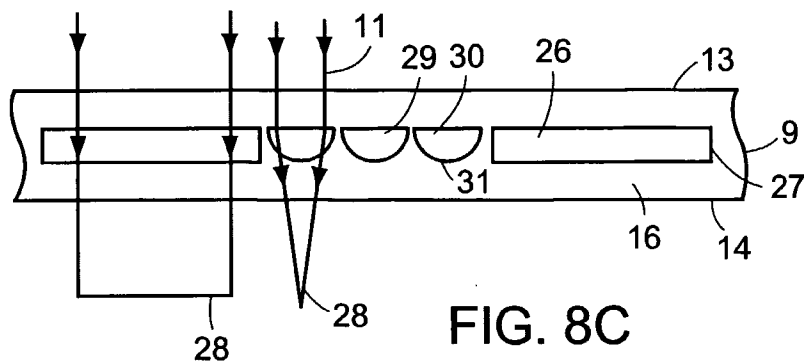


FIG. 8C

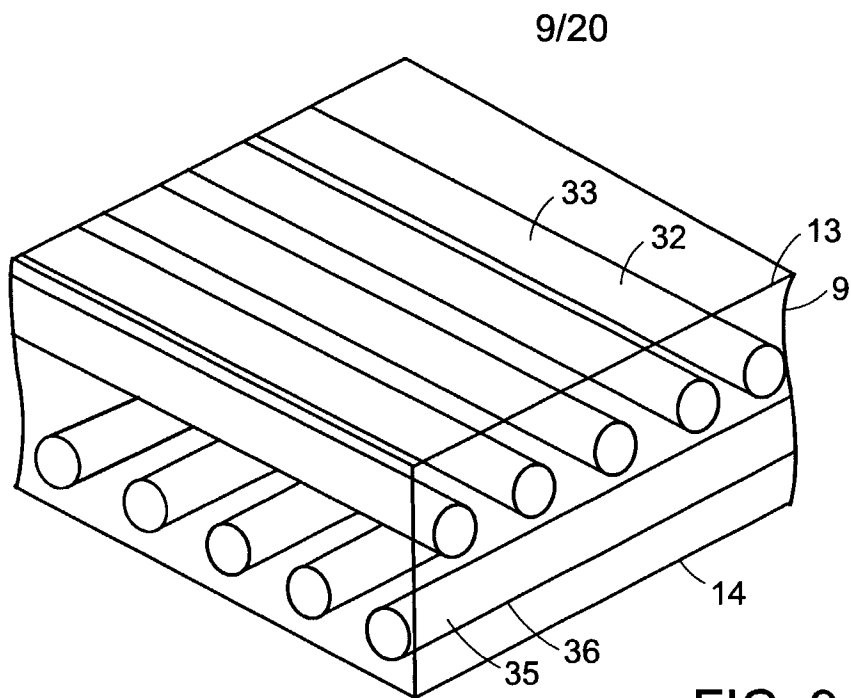


FIG. 9

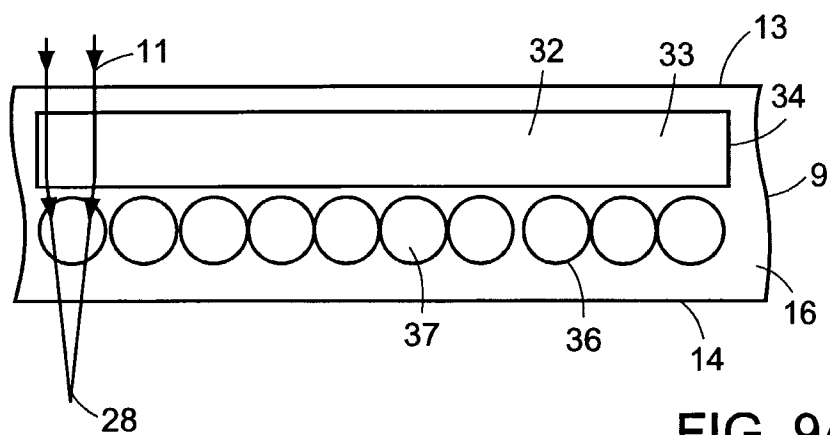


FIG. 9A

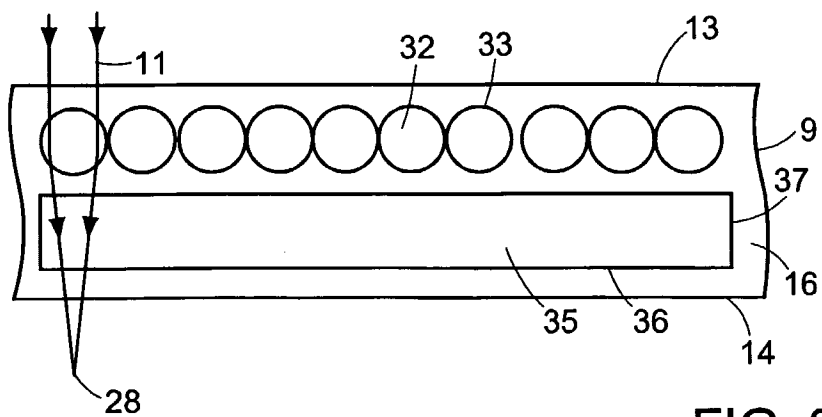


FIG. 9B

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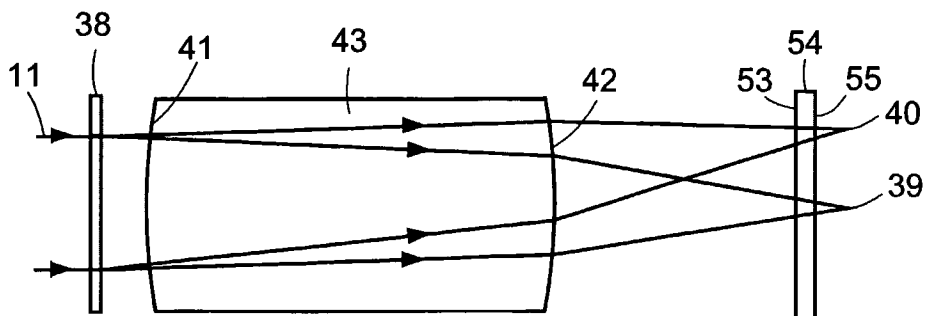


FIG. 10

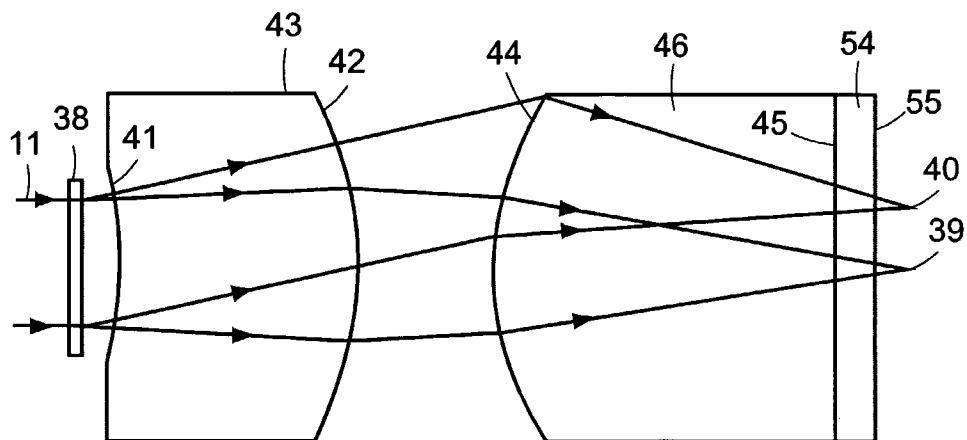


FIG. 11

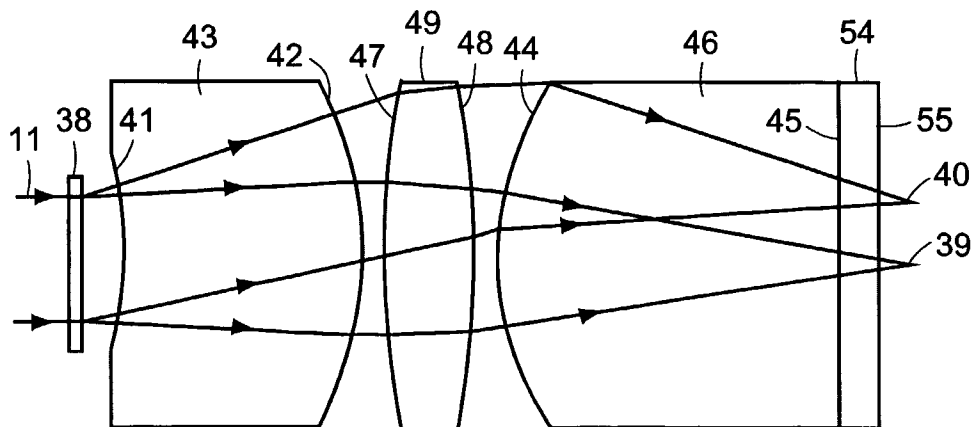


FIG. 12

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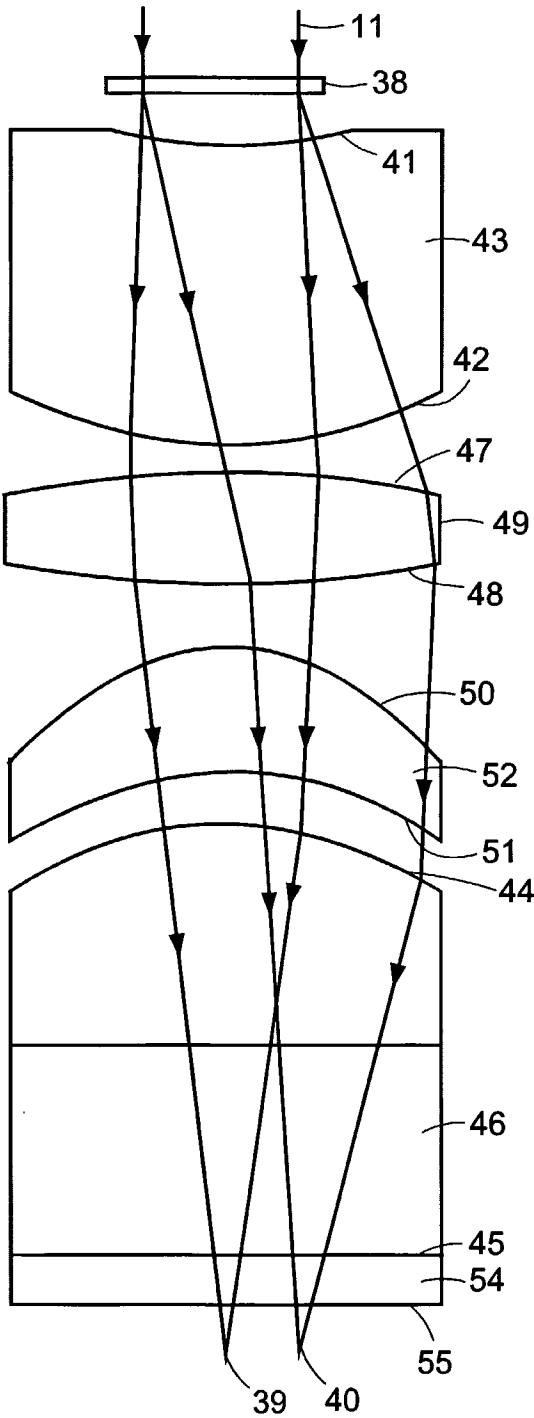


FIG. 13

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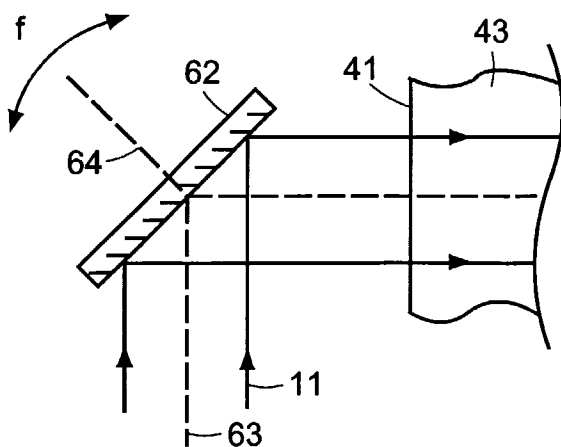


FIG. 14

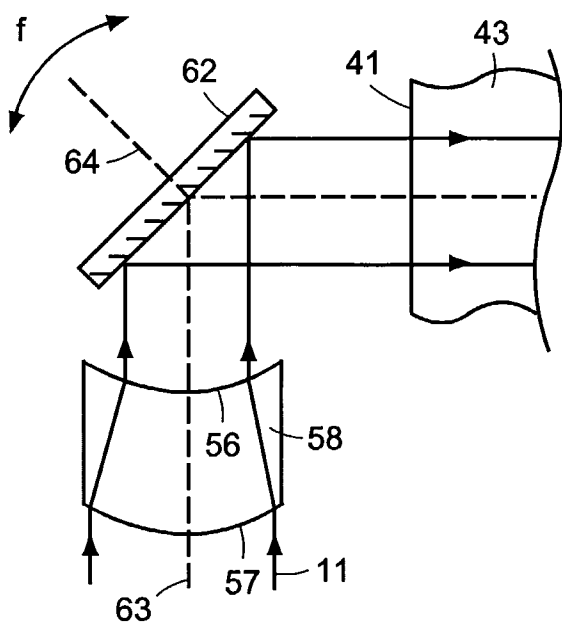


FIG. 14A

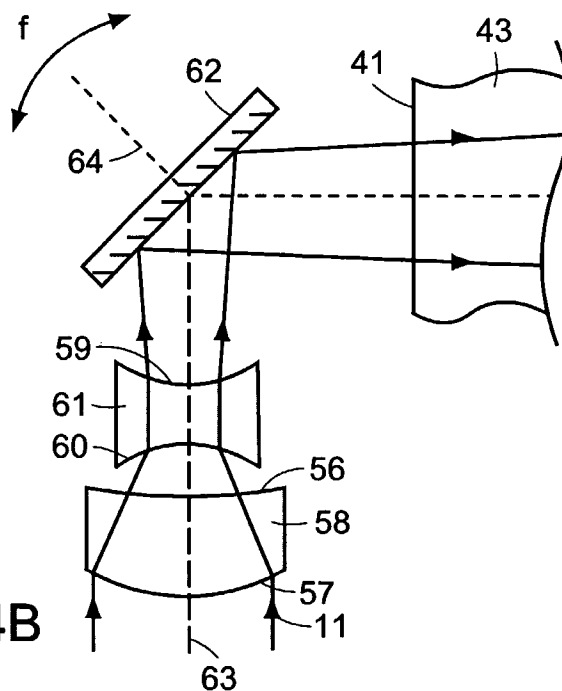


FIG. 14B

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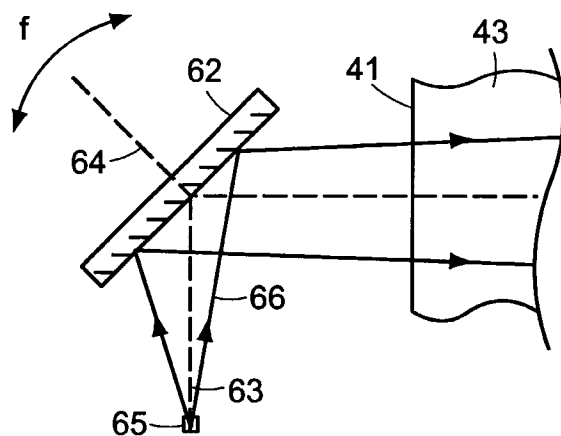


FIG. 15

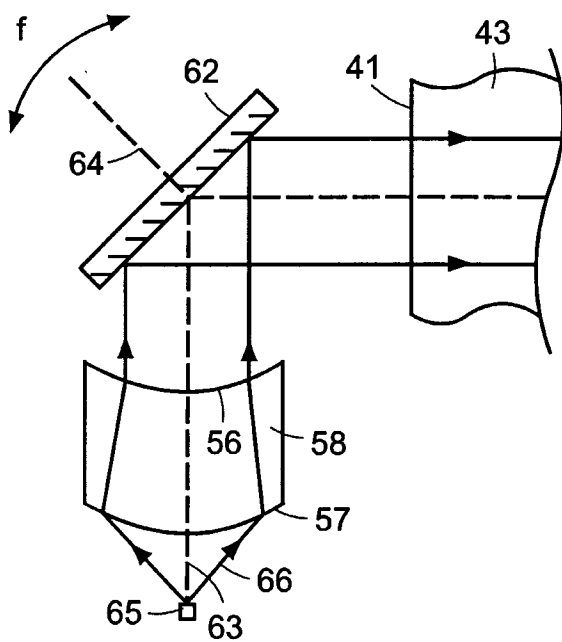


FIG. 15A

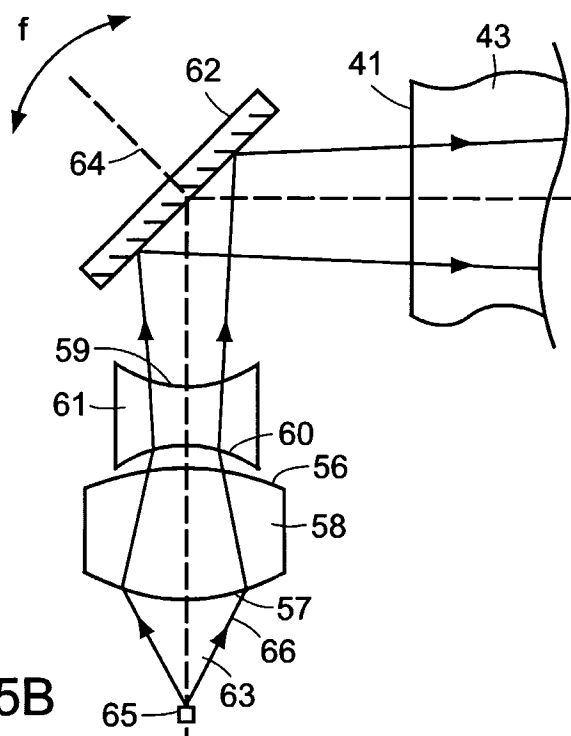


FIG. 15B

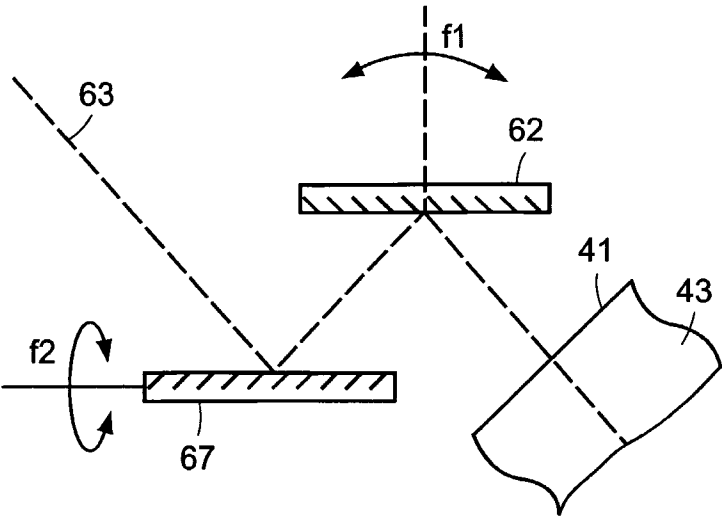


FIG. 16

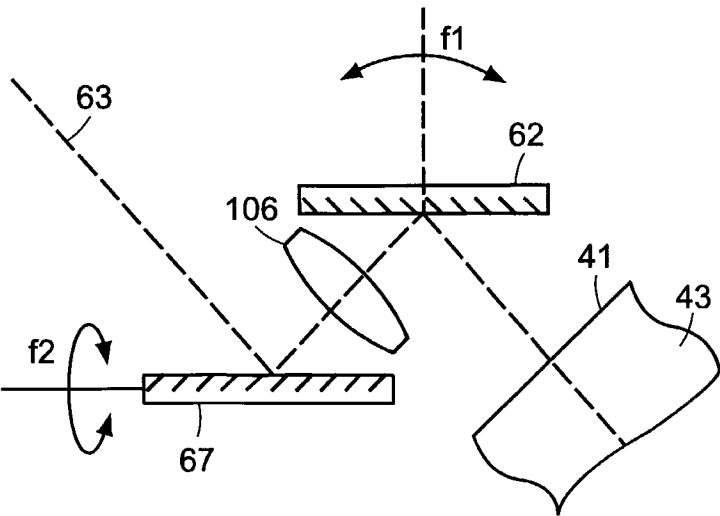


FIG. 16A

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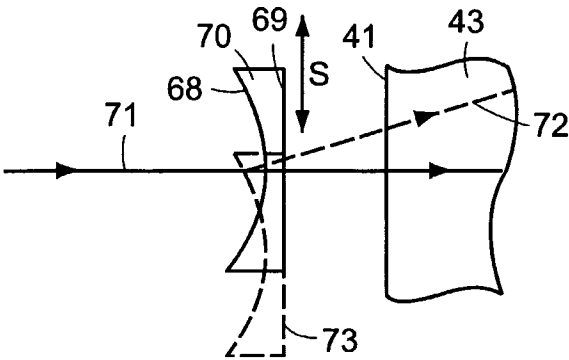


FIG. 17

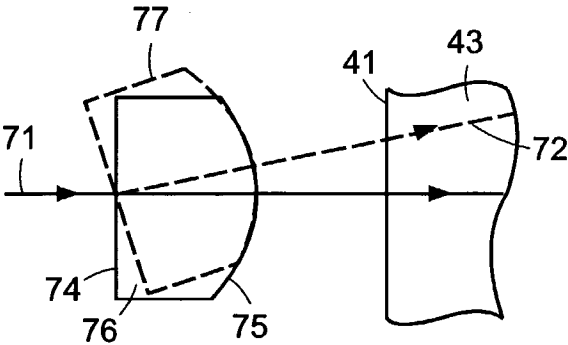


FIG. 18

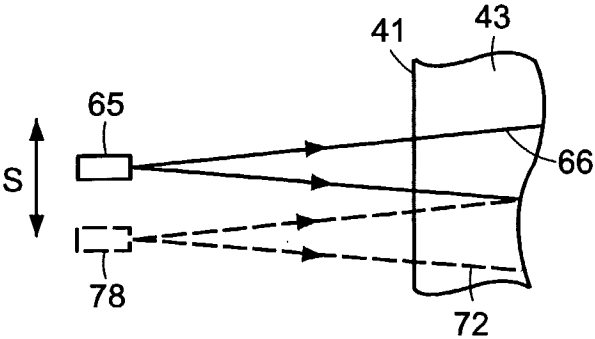


FIG. 19

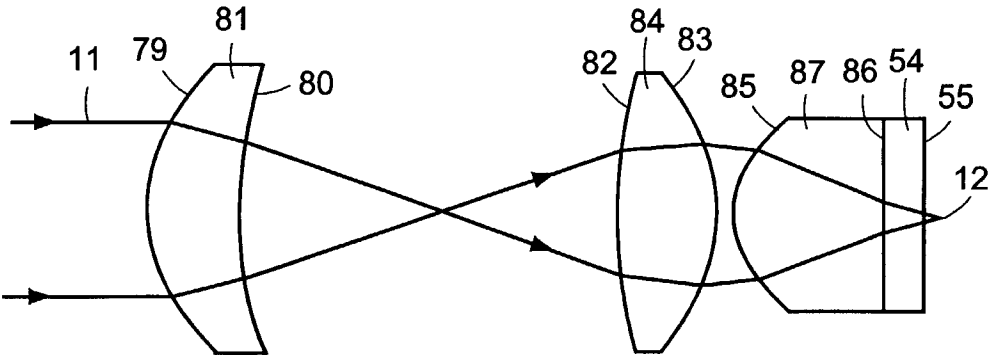


FIG. 20

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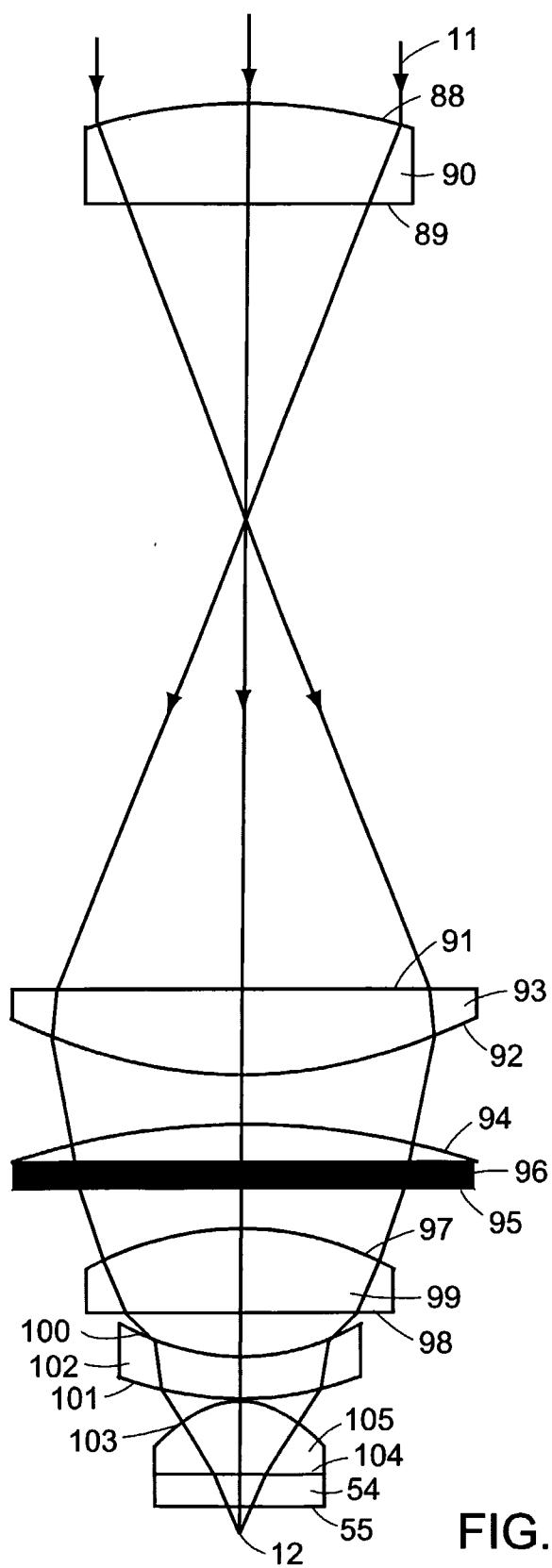


FIG. 21

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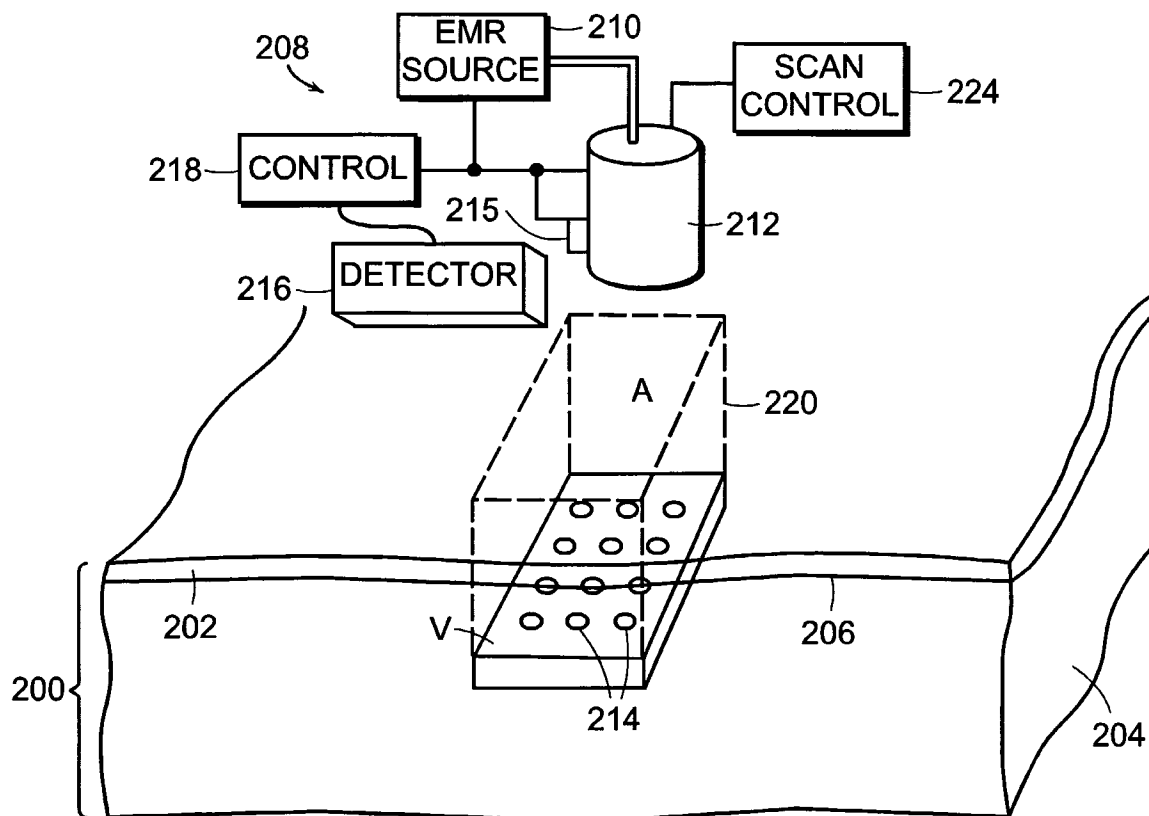


FIG. 22A

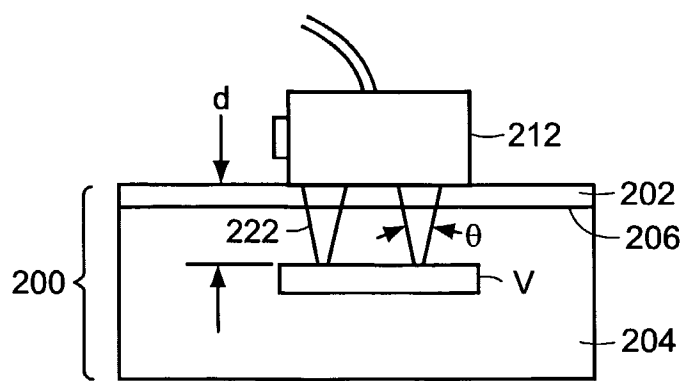


FIG. 22B

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Depth of damage, μm	Wavelength range, μm		NA range		Pulse width range, s
	broad	preferred	broad	preferred	
50-200	400 - 1880 & 2050-2350	800-1850 & 2100-2300	<3	0.2 - 1	<2
200-300	500-1880 & 2050-2350	800-1850 & 2150-2300	<3	0.2 - 1	<10
300-500	600-1380 & 1520-1850 & 2150-2260	900-1300 & 1550-1820 & 2150-2250	<2	0.2 - 1	<60
500-1000	600-1370 & 1600-1820	900-1250 & 1650-1750	<2	0.2 - 0.6	<120
1000-2000	670-1350 & 1650-1780	900-1230	<1.5	0.2 - 0.6	<120
2000-5000	800-1300	1050-1220	<1	0.2 - 0.4	<300

FIG. 23A

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FIG. 23B

Depth of damage, μm	Diameter of damage, μm	Wavelength, μm	NA	Pulse width, ms	Energy, J	Focusing depth, μm
300	50-100	2.2	0.3-0.5	<10	>0.00015	400-600
300	50-100	1.7	0.3-0.5	<10	>0.0007	400-600
300	50-100	1.3	0.3-0.5	<10	>0.003	400-600
300	50-100	1.54	0.3-0.5	<10	>0.0003	400-600
300	50-100	1.208	0.4-1	<10	>0.016	400-600
300	50-200	0.92	0.4-1	<10	>0.15	400-600
1000	50-200	1.7	0.3-0.4	<100	>0.01	1100-2000
1000	50-200	1.54	0.4	<100	>0.008	1100-2000
1000	50-200	1.3	0.4	<100	>0.1	1100-2000
1000	50-200	1.208	0.4	<100	>0.4	1100-2000

FIG. 23C

Depth of damage, μm	Diameter of damage, μm	Wavelength, μm	NA	Pulse width, ms	Power, W	Focusing depth, μm
500-1000	200-1000	2.2	0.3-0.5	>100	>0.5	600-1500
500-1000	200-1000	1.7	0.3-0.5	>100	>1.5	600-2000
500-1000	200-1000	1.208	0.3-0.6	>3000	>1.0	600-2000
500-1000	400-1200	0.92	0.3-0.6	>3000	>25.0	600-2000
2000-3500	1000-2000	1.208	0.3-0.4	>10000	>1.5	4000-6000

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 52481 A (COLLES MICHAEL JOHN ;MEDICAL LASER TECHNOLOGIES LIM (GB)) 26 November 1998 (1998-11-26) page 5, line 23 - line 28 page 11, line 15 - line 22; figure 3B ---	27-44, 46
X	WO 98 51235 A (GEN HOSPITAL CORP ;PALOMAR MEDICAL TECHNOLOGIES I (US)) 19 November 1998 (1998-11-19) page 17, line 19 -page 18, line 6 page 22, line 8 - line 28 ---	27-35, 37-43, 46
X	US 6 096 029 A (O'DONNELL JR FRANCIS E) 1 August 2000 (2000-08-01) column 3, line 9 -column 4, line 24 --- -/--	27-32, 36, 38-41, 43, 46



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Patent family members are listed in annex.

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

6 May 2002

Date of mailing of the international search report

14/05/2002

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Petter, E

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 71045 A (SHARON UZI) 30 November 2000 (2000-11-30) page 4, line 11 -page 5, line 31 ---	27-32, 35,36, 40-42,46
X	US 6 074 382 A (BALLE-PETERSEN OLAV ET AL) 13 June 2000 (2000-06-13) column 3, line 33 - line 59 column 5, line 37 - line 59 ---	27-32, 35,36, 40-42,46
P,X	WO 00 78242 A (EPPSTEIN JONATHAN A ;KUMAR KRISHNA (US); SPECTRX INC (US); HATCH M) 28 December 2000 (2000-12-28) abstract -----	27-36,46

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 01/49447

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9852481	A	26-11-1998	AU 7543298 A EP 1011498 A1 WO 9852481 A1	11-12-1998 28-06-2000 26-11-1998
WO 9851235	A	19-11-1998	AU 7568698 A EP 0991372 A2 JP 2002506362 T US 6273884 B1 WO 9851235 A1	08-12-1998 12-04-2000 26-02-2002 14-08-2001 19-11-1998
US 6096029	A	01-08-2000	US 6197020 B1 US 6106514 A	06-03-2001 22-08-2000
WO 0071045	A	30-11-2000	WO 0071045 A1 AU 3953299 A	30-11-2000 12-12-2000
US 6074382	A	13-06-2000	AU 8851898 A WO 9911324 A1 EP 1009485 A1 JP 2001514057 T	22-03-1999 11-03-1999 21-06-2000 11-09-2001
WO 0078242	A	28-12-2000	AU 5742600 A EP 1187572 A1 WO 0078242 A1	09-01-2001 20-03-2002 28-12-2000

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12 September 2002 (12.09.2002)

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(30) Priority Data:
60/272,745 2 March 2001 (02.03.2001) US

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Kultury prospekt, Apt. 228, St. Petersburg 195276 (RU). **BIRUCHINSKY, Sergey, B.**; 200/4 Moskovsky Prospekt, Apt. 94, St. Petersburg, 196135 (RU). **EROFEEV, Andre**; 38 Royal Crest Drive #7, North Andover, MA 01845 (US). **BELIKOV, Andre, V.**; 141/86 Naradnogo Opolcheniya Ave., St. Petersburg 198217 (RU).

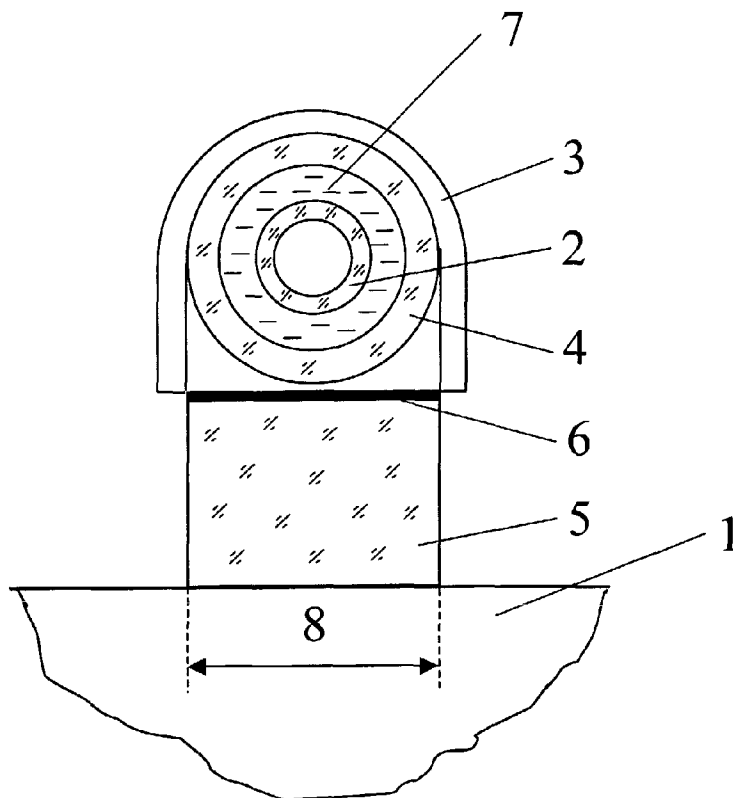
(74) Agent: **LANDO, Peter, C.**; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR PHOTOCOSMETIC AND PHOTODERMATOLOGICAL TREATMENT



(57) Abstract: This invention relates to apparatus for using a lamp for treatment of a patient's skin, which lamp is more efficient than prior such devices and to methods of using lamps for various skin treatments. The apparatus improves efficiency by minimizing photon leakage and by other enhancements. The invention also includes various enhancements to waveguides used for optical treatment on a patient's skin.



WO 02/069825 A2



Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- *without international search report and to be republished
upon receipt of that report*

APPARATUS AND METHOD FOR PHOTOCOSMETIC AND PHOTODERMATOLOGICAL TREATMENT

Related Application

5 This application claims priority to U.S. Provisional Application Serial
No. 60/272,745 filed March 2, 2001 entitled *Apparatus and Method for Photocosmetic
and Photodermatological Treatment*.

Field of the Invention

10 This invention relates to cosmetic and dermatological treatment using light, and
more particularly to improved methods and apparatus for such treatment.

Background

Optical radiation has been utilized for many years in medical and non-medical
15 facilities to treat various medical and cosmetic dermatology problems. Such problems
include, but are by no means limited to, removal of unwanted hair, treatment of spider
veins, varicose veins and other vascular lesions, treatment of port wine stains and other
pigmented lesions, treatment of psoriasis, skin resurfacing and skin rejuvenation for
treatment of wrinkles, treatment for acne, various treatments for reduction or removal of
20 fat, treatment for cellulite, tattoo removal, removal of various scars and other skin
blemishes and the like. Both coherent light, generally from a laser, and incoherent light,
generally from a flash lamp or other lamp, have been used in such treatments.

In recent years, increasing interest in this field has centered on the use of
incoherent light from various lamps both because of the potential lower cost from the use
25 of such sources and because such sources are considered safer, both in terms of potential
thermal or other damage to the patient's skin in areas overlying or surrounding the
treatment area and in terms of eye safety. However, existing lamp-base dermatology
systems have not fully realized either their cost or safety potential. One reason for this is
that, even the best of these devices, have no more than a 15% efficiency in delivering the
30 radiation generated to the treatment area. This means that larger and more expensive
optical sources must be utilized in order to achieve energy levels required for various
treatments. The energy lost in such devices can also produce heat which must be
effectively removed in order to prevent thermal damage to the system, to permit

-2-

applicators to be comfortably and safely held and to avoid thermal damage to the patient's skin. Apparatus for facilitating heat management also adds to the cost of these devices.

One potential source of thermal damage to the patient's skin in the use of these devices are local hot spots in the radiation beam being applied to the patient's skin. To avoid such local hot spots, it is desirable that the applied radiation be substantially uniform in intensity and in spectral content over substantially the entire beam. This has frequently not been true for existing lamp systems.

Another important factor in achieving both efficiency and safety is to optimize the lamp parameters, including the wavelength band or bands utilized, the intensity and the duration of radiation application for each particular treatment. Improved mechanisms for filtering of the lamp output to achieve selected wavelengths, for cooling the apparatus and for generating and controlling the radiation could further contribute to enhanced efficiency, reduced costs and greater safety.

A need therefore exists for improved apparatus and methods for the utilization of noncoherent radiation from a suitable lamp or other source to perform various medical and cosmetic dermatology treatments.

Summary of the Invention

In accordance with the above, this invention provides an apparatus utilizing a lamp for treatment of a patient's skin. The apparatus including a waveguide adapted to be in optical contact with the patient's skin and a mechanism for directing photons from the lamp to the waveguide to the patient's skin, which mechanism includes a sub-mechanism which inhibits the loss of photons from the apparatus. The mechanism may include a reflector, the reflector and waveguide being sized and shaped so that they fit together with substantially no gap therebetween. To the extent there is a gap between the reflector and waveguide it may be substantially sealed with a reflective material. The reflector is preferably sized and mounted with respect to the lamp so as to minimize the number of reflections for each photon on the reflector, the reflector preferably being small enough and mounted close enough to the lamp to achieve such minimum number of reflections. The reflector may be formed on an outer surface of the lamp. A tube may be provided surrounding the lamp with a gap between the lamp and the tube through

which fluid is flowed to cool the lamp. The reflector may be formed on the inner or outer surface of the tube. The reflector is preferably cylindrical in shape. The reflector may be a scattering reflector and may include a mechanism for controlling the wavelengths filtered thereby. Alternatively, the reflector may be formed of a material
5 which filters selected wavelengths of light from the light impinging thereon.

For some embodiments, there may be a gap between the reflector and the waveguide, a second reflector being mounted in said gap which, in conjunction with the reflector directs substantially all photons from the lamp to the waveguide.

The apparatus may also include a mechanism for selectively filtering light from
10 the lamp to achieve a desired wavelength spectrum. This filtering mechanism may be included as part of one or more of the lamp, a coating formed on the lamp, a tube surrounding the lamp, a filter device in a gap between the lamp and the tube, a reflector for light from the lamp, the waveguide, and a filter device between the lamp and waveguide. The filtering mechanism may be an absorption filter, a selectively reflecting
15 filter and a spectral resonant scatterer. The filter may include a multilayer coating.

The waveguide may be of a length selected to enhance uniformity of the light output from the lamp. The light output from the lamp may have resonances as a function of waveguide length, the waveguide preferably being of a length which is equal to one of the resonant lengths. The length of the waveguide is preferably greater than the smaller
20 of the width and depth of the waveguide at its end adjacent the lamp.

The apparatus also may include a mechanism for controlling the angular spectrum of photons within the patient's skin. More specifically, a gap may be provided between the lamp and the waveguide which gap is filled with a substance having a selected index of refraction. Where a tube surrounds the lamp, this gap is between the
25 tube and the waveguide. The length of the gap should be minimized and for preferred embodiments, the gap is filled with air.

The waveguide may have a larger area at a light receiving surface than at a light output surface and may have curved sides between these surfaces. The waveguide may also have a plurality of cuts formed therethrough, the cuts being adapted to have coolant
30 fluid flowed therethrough. The waveguide may also have a surface in contact with the patient's skin which is patterned to control the delivery of photons to the patient's skin. The waveguide may also have a concave surface in contact with the patient's skin, which

surface may be achieved by either the waveguide itself having a concave surface or a rim surrounding the surface having a concave edge. The depth of the concave surface is preferably selected to, in conjunction with pressure applied to the apparatus, control the depth of blood vessels treated by the apparatus. A mechanism may also be provided for
5 detecting the depth of blood vessels in which blood flow is restricted by application of the concave surface under pressure to the patient's skin, this mechanism permitting pressure to be controlled to permit treatment of the vessels at a desired depth.

Alternatively, the waveguide may have a skin contacting surface shaped to permit the application of selective pressure to the patient's skin to thereby control the depth at
10 which treatment is performed. The waveguide may also be at least in part a lasing or a superluminescent waveguide and may include a lasing waveguide inside an optical waveguide. Alternatively, a lasing or superluminescent material may surround the lamp, photons from the lamp being directed to this material.

A mechanism may also be provided which delivers a cooling spray to both the
15 patient's skin and the skin contacting surface of the waveguide just prior to contact. The waveguide may include a lower portion adjacent the patient's skin of a material which is a good conductor of heat and an upper portion of a material which is not a good conductor of heat, the thickness of the lower portion controlling the depth of cooling the patient's skin. Such control of cooling depth in the patient's skin may also be achieved
20 by controlling the thickness of a plate of a thermally conductive material having a cooling fluid flowing over its surface opposite that in contact with the patient's skin. A detector may also be provided which indicates when the apparatus is within a predetermined distance of the patient's skin, the cooling spray being activated in response to such detector.

25 The apparatus may also include rearward facing light output channel from the waveguide which leads to a backscattered detector, the channel being at an angle α to a perpendicular to the skin that only backscattered light reaches the detector. The lamp may be driven with a power profile which is one of the power profiles 44, 45 or 46 of Fig. 11. The waveguide may be formed as a unitary component with the lamp passing
30 through an opening formed therein.

The invention also includes methods for utilizing the lamp to perform various treatments on a patient's skin including:

a method for performing hair removal utilizing the parameter of Table 1;

a method for performing treatment vascular lesions utilizing the parameters of Tables 2, 3 and 4;

5 A method for performing skin rejuvenation utilizing the parameters of Tables 2 and 6;

A method for treating acne by killing bacteria, thermolysis of the sebaceous gland and/or killing spider veins feeding the sebaceous gland; and

treating pigmented lesions utilizing the parameters of Table 5.

10 The optimum spectrum for the optical radiation from the lamp supplied to the patient's skin is such that the ratio of the temperature at the treatment target to the temperature of the patient's epidermis is a selected value S , which is preferably greater than 1. Filtering may be used so as to provide one or more wavelength bands from the lamp output to achieve the above objective. A waveguide may be utilized having scattering properties which are dependent on waveguide temperatures and this feature
15 may be utilized automatically to protect the patient's skin. A reflecting absorbing or phase mask may be mounted or formed at the end of the waveguide to control regions of the patient's skin to which radiation is applied.

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the
20 invention as illustrated in the accompanying drawings, like elements in the various figures having the same or related reference numerals.

Brief Description of the Drawings

Fig. 1 and Fig. 2 are a cut-away side view and a longitudinal cross-section view
25 respectively of a lamp device for an embodiment of the present invention;

Fig. 1a and Fig. 2a are a cut-away side view and a longitudinal cross-section view respectively of a lamp device for another embodiment of the present invention;

Fig. 3 is a chart showing the absorption spectra for certain natural chromophores;

Fig. 4 is a chart of penetration depth spectra for different types of skin;

30 Fig. 5 is a chart showing typical arc-lamp emission spectra for selected parameters;

Figs. 6a and 6b are charts of temperature rise for the hair shaft and for the hair matrix relatively to temperature rise of the basal layer for white skin and dark skin respectively;

5 Figs. 7a – 7c are charts of initial lamp spectra and profiled spectra for different skin types and/or treatments;

Fig. 8 is a chart illustrating the dependencies of light illumination at 1mm depth and 3mm depth relative to illumination of the epidermis on the size of the light beam;

Fig. 9a and Fig. 9b are charts illustrating the distribution of light on the surface and at depth for a 10mm beam width and 15mm beam width respectively;

10 Fig. 10 is a chart illustrating the dependence of fluence improvement due to photon recycling on beam width.

Figs. 11a – 11c are diagrams of pulse power over time for three different pulse shapes.

15 Fig. 12 is a chart illustrating the relationship of wavelength in micrometers to the ratio of fluids at a shallow target (spider vein) to fluids at the epidermis.

Fig. 13a – 13l are schematic representations of various lamp cross-sections suitable for use in practicing certain aspects of the invention.

Figs. 14a and 14b are front cutaway views of lamps for alternative embodiments having different filter configurations.

20 Fig. 15a and 15b are perspective views of two alternative waveguide configurations suitable for use in practicing the teachings of this invention.

Fig. 16 is a perspective view of still another waveguide suitable for use in practicing the teachings of the invention.

25 Fig. 17 is a chart illustrating the dependence of the angular spectrum of the photons on the material placed between the outer tube of the lamp and the waveguide.

Fig. 18 is a side cutaway view of a lamp in accordance with an alternative embodiment of the invention wherein waveguide material substantially surrounds the lamp.

30 Fig. 19 is a chart illustrating the dependence of radiation uniformity on waveguide length.

Figs. 20a – 20d are side views (cutaway from Fig. 20c) of various waveguides suitable for use in practicing the teachings of this invention for different applications.

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Fig. 20e is a bottom view of a waveguide having a mask formed thereon.

Figs. 21a and 21b are side views of lamp configurations utilizing waveguides with lasing or superluminescent properties.

Fig. 22 is a chart illustrating the output spectrum for a lamp with a standard
5 waveguide and an illustrative output spectrum for a lamp having a lasing or
superluminescent waveguide of Fig. 21.

Figs. 23a and 23b are side cutaway views for two alternative embodiments incorporating novel filtering techniques.

Fig. 24 is a perspective view of a waveguide having novel cooling channels
10 formed therethrough.

Fig. 25 is a side view of a waveguide embodiment exhibiting unique cooling capabilities.

Fig. 26 is a side view of still another mechanism for cooling a waveguide.

Fig. 27 is a side view of still another cooling mechanism for a waveguide; and

15 Fig. 28 is a semi-schematic partially cutaway front view of an embodiment of the invention which provides a unique mechanism for detecting safe irradiation of a patient's skin.

Detailed Description of Preferred Embodiments

20 In Fig. 1 and Fig. 2, cross-sections of an illustrative device D for cosmetic and medical dermatological treatment of the skin 1 are shown; while most of the following discussion will be with respect to this device, this is not a limitation on the invention. The light source is represented by a linear tubular arc lamp 2 filled with a gas (Xe, Kr, Hg etc.) which lamp is enclosed in a glass or crystal tube 4 with cylindrical cross section.
25 The gap 7 between the lamp 2 and the tube 4 is filled with liquid or gas which may be pumped. A reflector 3 is placed around the tube with or without gap. The reflector may include a vacuum or galvanic high-reflective coating on a substrate having a curved tubular part and extending flat parts which reach (and preferably overlap) a waveguide 5 on all sides. The reflector includes end-plates 3, which are best seen in Fig. 2, and which
30 function to minimize any gap between reflector 3 and waveguide 5. To the extent any gap remains, it may be filled with a reflective material to minimize photon leakage. The reflector should also be made in a way such that gaps between the reflector and the

waveguide are minimized, not exceeding 10% of the total reflector surface, and that the reflection index is close to 1.00 for all wavelengths of radiation impinging thereon, and preferably not being less than 0.85 for any such wavelength. The reflector may be in the form of a thin flexible metal sheet with a reflecting surface facing the lamp. The reflecting surface may be a high-grade polished surface or may have a high-reflection coating. The coating may for example be silver or gold. The coating may be covered by a protective polymer film or thin non-organic dielectric in order to protect the coating against chemical degradation. The reflector coating may be a diffuse reflecting coating or a layer of powder (for example, BaSO_4) with low absorption in the spectral range of radiation used for skin treatment.

The reflector is optically coupled with waveguide 5. Direct light from lamp 2 and light from lamp 2 reflected by reflector 3 are coupled through filter 6 and the waveguide for delivery to the skin. The waveguide may be made of a glass or dielectric crystal. The radiation spectrum of the lamp may be converted into a spectrum which is optimum for treatment of the selected target in the skin, this transformation of the spectrum being provided by one of the following techniques, or a combination thereof: (a) absorption in the envelope of the lamp 2, (b) absorption in the liquid in gap 7, (c) absorption in tube 4, and/or (d) absorption or directed scattering in filter 6. Energy absorbed in the envelope of lamp 2, in the liquid in gap 7 and/or in tube 4 may be converted to a desired wavelength spectral range as a result of Stokes luminescence. For example, tube 4 may be of a fluorescent material or a liquid doped with dye may be employed in gap 7. These may act as a high-pass filter, fluorescing above a selected cut-off wavelength to move energy from blue to red. This may provide some protection for the epidermis without energy loss. Both converted radiation and unconverted radiation from the lamp may be delivered to the skin through waveguide 5.

Absorption may be provided by doping the above-mentioned components with, for example, ions of metals such as, Ce, Sm, Eu, Er, Cr, Ti, Nd, Tm, Cu, Au, Pt, organic and/or inorganic dyes, for example semiconductor microcrystals, or other suitable doping substances dissolved in liquid or glass. Filter 6 may be made as a multilayer dielectric interferometric coating on the surface of waveguide 5, on a transparent substrate or on a scattering medium. The scattering medium may be made as a special regular profile [on the surface of waveguide 5 produced, for example, by photolithography. It can, for

example, be a phase grating with spectral and angle transmission needed for treatment. Filter 6 may also be several stacked filter components, each filter working within a selected band or bands, some of which may be relatively narrow. Using several filters makes it easier to get a desired wavelength and, by using several filter components, no one filter component heats excessively. To the extent filtering is done by coatings on for example tube 4 and/or reflector 7, such coatings may also be multilayer.

Filter 6 can also be a cold or nonabsorption filter, which preferably has multiple layers, for example 30 layers. Such filters selectively reflect at the various layers creating interference which can eliminate undesired wavelengths. The reflected radiation can also be optically removed. However, while these so-called multilayer dielectric filters are advantageous in reducing heat management problems, they are generally not as effective in eliminating short wavelengths, and while filtering light very well for collimated beams, for high divergence lamp beams, they cannot provide the sharp cut off filtering needed for better wavelength selectivity. Other filters which might potentially be used as filter 6 include a film of a semiconductor material having an absorption band which is a function of an electric field applied thereto. Such semiconductor film may experience a Stark effect, wherein the cutoff frequency may be controlled by controlling a current or voltage passed through the material.

Scattering filters may also be used for the filter 6. Such filters may for example be formed of liquid crystal material, and electric current or field applied across the material controlling the wavelength where the refractive index of the components are the same, there being no scattering for such wavelengths permitting photons at these wavelengths to pass therethrough. Other wavelengths are attenuated by scattering. A scattering filter 6 can be multilayered with different materials or different materials can be used in a single layer of liquid crystal material to control the width and wavelength of the passband. Such passband would typically be both temperature and electric field dependent. Such a scattering filter should be designed to primarily scatter undesired wavelengths in large angle, including backwards. The large angle of the backscattered beam results in multiple reflections which further attenuate these unwanted frequencies.

Finally, an additional filter 2 may be mounted in channel 7 so that the filter is also cooled by the coolant in this channel. Other options, either currently known or developed in the future for both the location and type of filter used to achieve a desired

output wavelength band from device D may also be employed. There are three criteria which are important in selecting the location or locations for the filters and the type of filters utilized to achieve a desired output wavelength band from device D. These criteria are thermal design, the selection and positioning of the filter so as to minimize heat generated therein and/or to facilitate the removal of the heat therefrom. The second criteria, which is particularly important for the safety and efficacy of the treatment, is the sharpness of the signal cut-off for the full angular spectrum of the lamp. The third criteria is high transmission of the wanted wavelengths. . Filtering removes some of the energy of the beam and the more of this energy which is dissipated as heat in absorption filters, the lower the efficiency of device D.

Wave guide 5, at least during a treatment, is in optical and thermal contact with skin 1 of the patient in order to provide efficient coupling of light into the skin and cooling of the skin surface. For low mean power of the lamp (including low repetition rate of the treatment), cooling of the device components (lamp 2, reflector 3, absorbing filters) can be provided by natural convection. For high mean power of the lamp, additional cooling may be provided by a cooling system 11 (Fig. 2) flowing a liquid or gas through, for example, channel or gap 7, cooling in this case resulting from thermal contact of the cooled components with the flowing cooling agent, for example the liquid in gap 7. If cooling of the skin (epidermis) is necessary, waveguide 5 may be cooled before, during and/or after irradiation. Exemplary techniques for cooling waveguide 5 will be described below. Lamp power supply 10 provides the necessary power, duration and shape of lamp emission pulse for optimum irradiation of the skin target. An example of a suitable power supply is provided in co-pending application serial # 09/797,501, filed March 1, 2001. The optical layout of device D provides minimum losses of light and maximum reflection index for reflector 3 and the walls of the waveguide. Therefore, maximum efficiency in the utilization of energy from the lamp is obtained, permitting the cost of the device to be minimized. Photons reflected from the skin pass into device D through waveguide 5 and are directed back to the skin by reflector 3 and waveguide 5 with maximum efficiency, resulting in increased irradiation of the target in skin 1. These photons generally pass through lamp 2 with minimal loss of energy. This further increases the efficiency of energy utilization, permitting a further decrease in required lamp output, and thus in the cost of the device.

The optical system described above may sometimes be referred to as the optical system of skin irradiation with minimum photon leakage (MPL). The optical system of device D should also provide a relatively large spot size 8, 9 for the light beam on the surface of the skin 1, maximum uniformity of light intensity on the skin surface in order to decrease the possibility of epidermal damage and optimum light distribution for the destruction of a target inside the skin. Thus, in defining the parameters of the device, it is necessary to define parameters providing: 1) the desired spectrum of light to be delivered to the skin, 2) the size of the light beam on the surface of the skin with maximum uniformity of its spatial distribution, 3) optimum distribution of the light inside the skin, and 4) a desired fluence, duration and the temporal shape of the light pulse delivered to the skin. Conditions (1)-(4) depend on the selected target (blood vessel, hair follicle, dermis, etc.) and the patient's skin type. These conditions are considered taking into account the distribution of lamp light in the skin and the theory of selective photothermolysis (Anderson RR, Parrish J.; Selective photothermolysis: Precise microsurgery by selective absorption of the pulsed radiation. Science 1983; 220: 524-526) and extended theory of selective photothermolysis (Altshuler G.B., Anderson, R.R., Zenzie H.H., Smirnov M.Z.: Extended Theory of Selective Photothermolysis, Lasers in Surger and Medicine 29:416-432, 2001) .

Figs. 1a and 2a illustrate an alternative embodiment of the invention suitable for use where greater fluence is desired from a given lamp and a smaller spot size is either desired, or at least acceptable. Such a result would for example be acceptable where the treatment is at shallower depths rather than treatments at deeper depths. The desired results are achieved by using a concentrator waveguide 5' in place of the waveguide 5, waveguide 5' having walls which angle in so that the skin-contacting surface of the waveguide is smaller then the light-receiving side of the waveguide. However, while the straight walled waveguide 5 has substantially total internal reflection of photons therein, the angled walls of concentrator waveguide 5' permit some photon leakage through these walls or facets. To prevent photon loss as a result of this leakage, a reflector 3'' is provided adjacent each such wall, for example being coated on the wall, which reflector has high reflection, for example greater than 95%. Both recognition of the waveguide leakage problem and the use of reflectors 3'' or a comparable external reflector are considered novel and part of the invention.

Fig. 2a also illustrates another novel feature of this embodiment which compensates for the fact that lamp 2 may be longer than the length of the desired spot size. Normally this would result in photon leakage and the loss of photons. However, in Fig. 2a, reflectors 3' are provided in the gap between reflector 3 and waveguide 5' which reflectors are effective to couple rays or photons 83 from end portions of the lamp through waveguide 5' to the patient's skin. This embodiment thus result in a roughly 50% increase in the fluence improvement achieved by use of a concentrator waveguide.

The Propagation and Absorption of Lamp Light in the Skin

Differences in the propagation and absorption of lamp light as opposed to laser light in the skin results at least in part from differences in their selected range, the lamp spectrum being very wide (200-1000 nm), which is thousands to tens of thousands times wider than the spectral range of laser radiation. The angular spectrum of a lamp source may be as wide as $\pm 180^\circ$. That is hundreds to thousands times wider than the angular spectrum of laser radiation. Therefore the propagation and absorption of lamp light in the skin differ considerably from that of a laser. In the near UV, visible and near IR ranges, the absorption of water, hemoglobin, oxyhemoglobin, melanin, lipid and protein, as well the absorption of dopants (carbon particles, molecules of organic and inorganic dyes), may be used for optical/ light therapeutic treatment of the skin. In Fig. 3, spectra are shown for the main natural skin components, namely 12-water, 13-arterial blood (95% hemoglobin, 5 % oxyhemoglobin), 14-venous blood (65% hemoglobin, 35% oxyhemoglobin), 15 – pheomelanin (red hair), 15'-eumelanin (dark hair, epidermis), 16 – reduced scattering coefficient of the skin. In Fig. 4, the depth dependences at which three times attenuation of a collimated wide light beam occurs as a function of wavelength is shown for different types of skin (17-white blond, 18-white brunet, 19-japanese, 20-indian, 21-mulatto, 22-african-american).

In Fig. 5, typical arc lamp emission spectra (without luminescent bands containing minor parts of the total energy) for different durations and equal energies of light pulse are shown. These curves are obtained for the same lamp having a 5x50mm discharge gap filled by Xe under a pressure of 450 torr with the following pulse durations: 24 – 1ms, 25 - 5ms, 26 – 20ms, 27 – 50ms, 28 – 100ms, 29 – 200ms, 30 – 500ms. The different pulse durations correspond to different color temperatures of the

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lamp which determines the shape of the lamp emission spectrum. Thus, as can be seen from Fig. 5, changing the pulse width can be used to shift both the output spectrum and the color temperature. As can be seen from Figs. 3, 4, and 5, the spectrum of the lamp covers the absorption bands of all chromophores in the skin; therefore the lamp can be
5 use for all skin chromophores. However, in order to achieve optimum treatment and utilization of light energy, it is necessary to provide the correct combination of color temperature of the lamp, spectral filtering, size and divergence of the beam at the output of the waveguide, intensity, fluence, duration and temporal shape of light pulse. These conditions depend strongly on the type of therapy. The apparatus described in the
10 present invention is intended mainly for cosmetic procedures and treatment of dermatological problems which influence cosmetic properties of the skin.

Among these procedures, the following are of particular interest: management of hair growth; treatment of vascular lesions and pigmented lesions; and improving skin structure including reducing wrinkles/ skin rejuvenation, coarseness, low elasticity,
15 irregular pigmentation, inflammatory acne and cellulite.

Management of Hair Growth

If selective, substantial damage to a hair bulb takes place, it becomes possible to stop or delay hair growth and to decrease hair size and pigmentation. Conversely, very
20 light damage of the hair matrix can accelerate hair growth and pigmentation. Damage to follicle stem cells which are located in the outer root sheath at the level of the bulge can result in permanent hair removal. Permanent hair removal is also possible if dermis surrounding a hair follicle is damaged so that the follicle structure is fully or partially replaced by connective tissue, i.e., a microscar appears in place of the follicle.
25 Photoepilation takes place due to the heating of follicles as a result of light absorbed by melanin contained in the hair matrix or hair shaft. The greatest concentration of melanin is in the hair matrix located inside the dermis or subcutaneous fat at a depth of 2-5 mm from the skin surface. Thus, in order to provide management of hair growth, the first damage targets are the hair bulb and the stem cells at the depth of the bulb which is
30 approximately 1-1.7 mm from the skin surface, and a second damage target is the matrix located at 2 to 5 mm. A significant problem in hair growth management is preserving the overlying epidermis which also contains melanin. From Figs. 3, 4, 5, it can be

concluded that, in order to provide selective damage of hair follicles, the radiation spectrum should be 360-2400 nm. The short-wavelength part of the spectrum is limited by potential damage to proteins, including DNA. The upper wavelength is limited by strong water absorption. Effective absorption of melanin takes place in the range of 360-1200 nm. However, a total cut-off of the 1200-2400 nm portion of the spectrum is not desirable because deeply penetrated infrared light is absorbed by water and provides additional, but not selective, heating of the hair follicle. In this case, the spectral components which are close to water absorption bands (Fig. 4) near 1.4 μm and 1.9 μm should be eliminated from the radiation spectrum because these wavelengths are absorbed in the epidermis and may cause overheating thereof, leading to patient pain and potential epidermal destruction. The best way to filter these wavelengths is to use water as a "water" spectral filter. In device D (Fig. 1, 2), filtering water is placed in the gap between lamp 2 and tube 4. An appropriate thickness for this water to effect filtering is estimated to be within the range 0.5–3 mm. Since the absorption by melanin is basically within the range of 360–800 nm, the color temperature T_c of the lamp should be within $T_c=3000-10000$ °K (Fig. 5). Filtering of short-wavelengths is determined by the type of the skin. In Figs. 6a,6b, the dependence of the ratio of the hair matrix (3mm depth) temperature to the temperature of the basal layer (31), and the dependence of a ratio of the hair shaft temperature at the depth of the bulge (1mm) to the temperature of the basal layer (32) on the wavelength of the short wavelength cut-off filter under fixed energy of lamp pumping are shown. The same dependences for pressed or cooled skin where blood is removed from small vessels in the dermis are shown by dotted curves (33,34). From Fig. 6a, it is seen that in the case of white skin, the use of short-wavelength radiation substantially increases the efficiency of stem cell destruction and the pressing or cooling of the skin causes the same result for the hair matrix. In this case, the thermal influence in the epidermis increases, but is lower in absolute value than in the pigmented hair shaft and hair matrix. In strongly pigmented skin (Fig. 6b), the short-wavelength cut-off should be raised. The dependence represented in Figs. 6a, 6b indicate the requirements for the filtering of short-wavelength radiation for different types of skin. This data is represented in table 1.

In Fig. 7a, the spectrum of the lamp under $T_c = 5000^\circ\text{K}$ (35) and after filtering (36) is represented. This spectrum is optimized for treatment on mulatto skin with

brown-black hair. With this spectrum, maximum heating of the hair matrix without overheating the epidermis is achieved for a defined energy of lamp pulse. The upper or far wavelengths of the spectrum are filtered by a water filter in gap 7 of 1 mm thickness.

In Fig. 7b, the spectrum of the lamp for $T_c = 6000^\circ\text{K}$ before filtering(35) and
5 after filtering (36) is represented. This spectrum is optimized for treatment of deep (0.3-1.0 mm depth) vascular. In Fig. 7c, the spectrum of the lamp for $T_c = 3000^\circ\text{K}$ before filtering(35) and after filtering (36) is represented. This spectrum is optimized for treatment of collagen due to water absorption.

The spectrums 36 shown in Fig. 7a-7c will each be referred to as a profiled
10 spectrum of lamp [PSL]. The spectrum of the lamp is attenuated (profiled) for both the short and far or long wavelengths in order to provide maximum heating of the target while not overheating the epidermis. This condition can require several filtered bands (see spectra in tables 2-4). The optimum PSL for a given procedure may be one or more wavelength bands obtained, generally by filtering, from the output spectrum of the lamp,
15 the band or bands being selected so that the ratio of the temperature rise of the target (hair shaft, matrix, vessel, vein, pigment lesion, tattoo, etc.) to the temperature rise of epidermis is more than a certain numbers S, which number S is dependent on from the level of safety for the procedure. The higher the number S, the higher the safety level. To maximize efficiency of the lamp, S should be about 1.

20 The dimensions of the beam are also important. It is known that for increasing beam size and constant intensity (fluence) on the surface, the intensity (irradiance) of light at depth increases and saturates once some transverse dimension of the beam is achieved (see Fig. 8).

When this dimension is increased, the ratio of illumination at a depth of 3-5 mm
25 (where the hair bulb is located) to the illumination of the epidermis reaches a maximum, thus making it possible to provide maximum temperature at the hair bulb or stem cells with minimum risk of epidermal damage/destruction.

Fig. 8 shows the dependence of the ratio of the heat production on a melanin target in the skin at a depth of 1 mm ($F = 1 \text{ mm}$) (curve 37) and 3 mm ($F = 3 \text{ mm}$) (curve
30 38) to the heat production at the basal layer F_{epi} with the same melanin concentration at the target for a lamp with color temperature $T_c = 6000^\circ\text{K}$ and the appropriate PSL on the size of the beam formed by the device D shown in Figs. 1, 2. The length 9 of the beam is

fixed and equal to 45 mm. Usually this length is limited by the length of the lamp discharge gap. The width of the beam is varied within a range of 1-45 mm. Fig. 8 shows that for a deep target in the skin, the width of the beam should be more than 10 mm (minimum beam width $d=10$ mm). Best results are achieved when the width d is greater than 15 mm.

The second advantage of the wide beam is uniformity of illumination of the hair follicle at depth. For a beam of width <10 mm, the distribution at depth has a gaussian shape with sharp maximum. Therefore a large percentage overlapping of the beams when scanning along the skin is necessary for uniform irradiation of the follicles. This leads to a considerable decrease in the rate of treatment, decrease in efficiency of energy utilization and increase in the cost of the procedure. Further, the possibility of "missing" follicles because of the non-uniform overlapping, and hence the rapid growth of missed hair, still exists. The distributions of light intensity produced by device D for a beam of 10 mm (curves 39, 40) and 16 mm (curves 41, 42) are represented in Fig. 9. The curves 39 and 41 show the distribution on the surface and the curves 40 and 42 describe the distribution at depth. Fig. 9 shows that uniform overlapping of beams with 10 mm width needs at least 27% (Fig. 9) overlap whereas only 15% overlap is necessary for beams of 16 mm width.

A third advantage of wider beams becomes apparent in lamp-based devices with an MPL optical system as is shown in Figs. 1, 2. As is discussed above, for these MPL systems, photons reflected from the surface are returned back to the skin and increase the utilization efficiency of the lamp energy. This effect may increase irradiation inside the skin up to three times, if the lamp-based devices with MPL optical system has very low leakage of photons. However it is greater if the size of the beam is increased. Fig. 10 shows the dependence of skin irradiation amplification g caused by the return of the photons reflected from the skin on the size of the beam d for the same conditions as for Fig. 8. Fig. 10 shows that the effect of amplification is achieved if the beam width is >10 mm. Thus, the minimum dimensions of the beam for the hair management application is preferably about 10 mm, >15 mm being preferable.

The requirements of pulse duration and temporal shape are now considered as well as intensity and light flow. In order to provide temporal injury or growth stimulation, critical parts of a follicle include the hair bulb, and more important the hair

matrix, of a hair follicle in anagen stage. The thermal relaxation time of a hair matrix for a terminal hair with a diameter of 30–120 μm is within the range of 0.6-10 ms. (See Altshuler G.B., Anderson R.R., Zenzie H.H., Smirnov M.Z.: ; Extended Theory of Selective Photothermolysis, Lasers in Surgery and Medicine 29:416-432, 2001).

5 Therefore, pulses with duration up to 10 ms are suitable and effective for the destruction of a hair matrix or the switching of the hair growth cycle due heating of the hair matrix. Hair papilla may be damaged by direct absorption of light in the micro vessels. However, a better way to damage the papilla of a follicle may be the diffusion of a thermal front at a temperature sufficient to damage tissue ($\sim 65^{\circ}\text{C} - 75^{\circ}\text{C}$) from the hair matrix to the
10 papilla. The time for this diffusion, which is sometimes referred to as the thermal damage time (TDT), is 15-20 ms for hair with the dimensions previously discussed. TDT of a whole follicle structure, i.e. the time of the propagation of the front of thermal tissue damage from the hair shaft or hair matrix to the outer junction of hair follicle, is approximately 30-2000 ms depending on the dimension of the follicle and on radiation
15 intensity. In this case, the intensity should be limited in order to maintain absorption by melanin of hair shaft or hair matrix to the end of the pulse, (i.e., to prevent destruction of the hair shaft or hair matrix during the pulse).

For a hair shaft, this corresponds to heating the shaft to a temperature of less than 250°C . At the same time, the pulse should be long enough to deliver sufficient energy to
20 the follicle for its destruction. Thus, the optimum pulse duration is TDT of the follicle structure as a whole. TDT of hair follicle (30-2000 ms) is essentially longer than the thermal relaxation time of the absorption layer in epidermis (320 ms). When long pulses with TDT duration are used, the temperature of the epidermis must be decreased by cooling so that much more energy may be applied to the follicle without risking damage
25 to the epidermis. The effect of long pulse can not be simulated exactly by a train consisting of several short (up to 10 ms) pulses because the peak intensity of the short pulse may be high enough to destroy the chromophore in the hair follicle or to damage the epidermis. The temporal shape of the pulse is also important. Thus the shape of the pulse depends on the nature of the epidermis, dispersion of the hair diameters and length,
30 hair shaft pigmentation and the cooling.

In Fig. 11, three main pulse shapes used for maximum hair follicle destruction are shown, the shapes being dependent on these three factors. These pulses will be referred

to as the profiled pulses (PP). Curve 44 is the shape of a lamp pulse with front τ_f and trailing edge τ_r durations, where $\tau_f < \tau_r$. The duration τ_f should be considerably longer than the thermal relaxation time (TRT) of the epidermis, but much shorter than TDT of the target $\text{TRT} \ll \tau_f \ll \text{TDT}$. The duration τ_r should be approximately equal to TDT.

- 5 The heating mode provided by pulse type 44 allows rapid heating of the chromophore in the target (hair shaft or hair matrix) up to a maximum temperature where the chromophore is still not bleached and is viable and then maintains these temperatures (i.e. does not overheat the chromophore). The temperature of the chromophore (hair shaft or hair matrix) is thus kept nearly constant and close to the temperature of
- 10 chromophore destruction. The pulse temperature has a substantially uniform shape.

For a pulse with shape 44 with rapid heating of the hair shaft or hair matrix up to maximum temperature, the efficiency of the absorption increases due to the denaturation of the surrounding tissues and scattering increase. Carbonization of chromophore and surrounding tissues may also take place causing an increase in absorption. If pre-cooling

15 of the epidermis takes place, epidermal temperature and the temperature of surrounding tissue (including the contact cooler) is low and partially compensates for the heating effect by the front part of the pulse. Moreover as soon as $\tau_f \ll \text{TRT}$ during heating by the front part of the pulse, the epidermis is cooled due to the heat leakage into surrounding pre-cooled tissues. The decrease of power at the edge of the pulse protects

20 the epidermis against overheating during the input of energy to the skin at the edge of the pulse. In this case, parallel cooling using the contact waveguide is especially effective.

Curve 45, a quasi-uniform pulse, has a pulse rise duration τ_r and a flat top of duration τ_m . The power of the pulse on the top is selected in such way that $\tau_m \approx \text{TDT}$ is realized only near the end of the pulse and the temperature of the chromophore reaches

25 maximum value just before the absorption of the chromophore decreases. This heating mode of curve 45 requires less power but longer TDT and higher total energy. The advantage of this mode is that it does not require as strong pre-cooling as the mode described by curve 44 and the output power of power supply 10 may be minimized.

Curve 46 describes a light pulse with long rise time τ_1 and a short higher power

30 end pulse with the duration τ_2 . Such pulse may be most effective for the treatment of patients who have high dispersion of pigmentation and hair diameters. In this case, follicles with strong absorption are initially damaged and at the end of the pulse the

follicles with low absorption which need higher power are damaged. The light pulse with shape 46 may be effective due to the pre-heating effect of the front part of the pulse with the duration τ_1 . In this case, in the interval τ_1 (0.1 – 5 s), the temperature of the lamp is low and it radiates much energy in the range of water absorption. Therefore, at this stage, pre-heating of the epidermis and hypodermis (where hair bulb is situated) takes place, and the temperature of the epidermis is kept low due to the parallel cooling by the contact waveguide 5. During stage τ_2 , which lasts approximately TDT, damage of the target takes place, while the temperature of the target is 45 – 60°C and damage requires little energy. Functions describing the front and edge parts of light pulses 44, 45, 46 may be stair-like, linear, quadratic, exponential or other similar functions. In Table 1, the modes of hair management using the proposed device are represented. These modes are obtained based on numerical optimization taking into account the requirements of optimum energy utilization and desired cost.

15 Vascular Lesion

The described device is most effective for the treatment of vascular lesions with careful optimization of the filtered lamp spectrum, pulse duration and shape. For the treatment of shallow vascular lesions, the size of the beam is not too important. For the treatment of deep veins, requirements on beam size are the same as for hair management considered above. The criteria for spectral optimization are similar to the above. However the spectra of hemoglobin shown in Fig. 3 should be taken into account. For white skin, the PSL can include blue light that is very effectively absorbed by blood and needs lower energy than for the yellow spectrum. Using blue light makes the device more effective. The duration and the shape of the pulse are selected to cause thermal damage of the vessel's wall as soon as thermal necrosis of the endothelia takes place. The power of the pulse should be enough to keep the temperature of blood within the range 65–75°C for TDT but never exceed 100°C. The shape of the pulse is selected from the three shapes represented in Fig. 11. It may be formed in the same way as for hair management. The application of the selective epidermal cooling allows a lamp spectrum to be used which is wider in the short-wavelength range and provides higher efficiency of lamp energy. In Table 2 (superficial spider vein, rosacea, plexus, port-wine stain, gemangioma, etc), 3 (deeper vein, feed vascular) and 4 (deep large leg vein), the modes

of treatment of a vascular lesion situated at different depths using the described device are represented on the basis of numerical optimization. As shown in tables 2, 3, optimum PSL for vascular treatment can include one, two (Fig. 7b) or three bands.

5 Pigmented Lesion

The described device may be used for the treatment of different pigmented lesions. Pigmented lesions are usually situated at depths of 50 – 300 μm ; therefore, the size of the beam is not essential. In the spectrum of the radiation, all components that could be absorbed by melanin, including UV radiation, may be present. The duration of
10 the pulse should be less than the shortest times of TRT for a pigmented lesion or layer thickness where lamp radiation penetrates. Some pigmented lesion treatments require damaging layers of surrounding tissue. In this case, the duration of the pulse should be less than the TDT of all target. Cooling may be used to reduce the pain effect and decrease the risk of blistering. In Table 3, the modes of treatment of pigmented lesions
15 using the described device are represented on the basis of numerical optimization. Highly pigmented and/or deep lesion can be treated with a redder spectrum. Lowly pigmented and/or superficial lesions can be treated with a spectrum which is more in the green or blue.

Similar parameters can be used for tattoo treatment, but the optimum PSL for this
20 treatment is one or several bands of wavelength filtered from a lamp spectrum for which the ratio of temperature rise of the tattoo particles or drying tissue to temperature rise of the epidermis is more than 1.

Skin Rejuvenation

25 Limited damage of the skin may stimulate the replacement of the damaged tissues by new tissue and improve the cosmetic properties of the skin. The described device may be used for this purpose, damaging tissue and surrounding blood vessels in the papillary and reticular dermis, pigmented basal membrane and collagen in the dermis. In the first two cases, the modes of the treatment and the parameters of the
30 device should be close to that described above for the treatment of vascular lesions and pigmented lesions. In order to provide damage to deeper layers of the dermis (100 – 500 μm), absorption of water in combination with cooling of the skin surface may be used. In

this case, the color temperature of the lamp should be low and spectral filters should select spectral components which are highly absorbed by water (see PSL of Fig. 7c). In Table 6, the modes of skin rejuvenation due to damage of the dermis at a depth (100 – 500 μm) are represented on the basis of numerical optimization. For skin rejuvenation, the profiled pulses (PP) (Fig. 11) may be used. Thus PP of curve type 44 are optimum for the destruction of thin layers of the dermis. PP of curve type 45 is optimum for the destruction of the deeper layers. PP of curve type 46 may be used to combine damage of the dermis due to the absorption of water and destruction of blood vessels and dermis closely situated to the basal layer. In this case, the pulsed irradiation according to curve 44 may be combined with switching of the device output spectrum. On the long part of curve 44 with duration τ_1 , the power of the lamp is low and the spectrum is shifted to the range of water absorption. In the short part of the pulse τ_2 , the power is increased rapidly and the spectral maximum moves towards the visible or UV range. The duration τ_2 may be shorter than TDT of thin vessels (0.1 – 10 ms) and thin layers of the dermis (1- 20 ms). In order to provide switching of the spectrum, an additional spectral filter with controlled transmission or nonlinear spectral filter with transmission spectrum dependent on the power of the lamp radiation may be used.

New collagen growth can also be achieved as the result of an inflammatory reaction around small blood vessels in papillary dermis. In this case, the treatment parameters are the same as in Table 2. This mode of treatment can be either in addition to or instead of the mode of achieving collagen growth previously discussed.

Acne Treatment

Acne vulgaris is one of the most common skin diseases and relates to hyperactivity of the sebaceous gland and acne bacteria. Lamp radiation may be used to reduce bacteria growth and for temporal or permanent damage of the sebaceous gland structure. In order to reduce bacteria growth, the photodynamic effect may be used on the porphyrins contributing to bacteria. Porphyrins have a modulated wide spectrum of absorption from red to the UV range. The optimum treatment mode is prolonged (1-30 min) irradiation of acne by lamp light in CW mode in the spectral range 340-1200 nm with the spectrum band(s) utilized being selected to match the absorption spectrum of the porphyrins. The intensity of the light delivered to bacteria (depth is 0–3 mm) should be

as high as possible. In the proposed device, it is provided by intensive parallel cooling of the epidermis simultaneously with irradiation. Thus, due to the cooling (-5 - +5C) , blood circulation in vessels of the papillary dermis is reduced and transmission of the skin dermis for blue and UV light is increased. Increased transmission may also be achieved
5 due to pressure applied to the skin by waveguide 5.

According to the described method, it is possible to deliver to the skin lamp radiation with an intensity up to 20 W/cm² within the range 340–900 nm. Thus the short-wavelength part of the spectrum, for example 410 nm, is absorbed more intensively by propherin, but this absorption is reduced considerably at a depth ~ 0.5mm. At the same
10 time, the red radiation is weakly absorbed by propherin, but is barely reduced at a depth 1 mm. Therefore, a wide spectrum is most effective to injure the bacteria via the photo dynamic effect.

The second and more effective mechanism of the treatment of acne vulgaris is reducing the sebum production function of the sebaceous gland. This may be achieved
15 by the destruction of sebocytes or the coagulation of blood vessels supplying the sebocytes with nutrient substances. During periods of hyperactivity of sebocytes, the blood vessel net is filled by blood. The combination of a wide-band (340 – 2400 nm) light source with water filtering which attenuates radiation in the range of water absorption bands (1400 - 1900 nm) and with intensive cooling (-5 - +5C) of the
20 epidermis and pressing of the skin, allows selective damage of spider veins supplying the sebaceous gland. Thus, the duration of the pulse should correlate with TDT of these vessels and may be about 1–100 ms for an energy density 5 – 50 J/cm² ,the energy density increasing with increasing pulse length. In order to totally or partially damage the sebaceous gland, it is possible to use a direct diffusion channel between the skin
25 surface and the sebaceous gland. This channel is represented by the gap between the hair shaft and outer root sheath and usually is filled by sebum. Molecules and particles with dimensions less than 3µm with lypophil properties may diffuse through this gap and accumulate in the sebaceous gland. Further, these molecules and particles may be used for the selective photothermolysis of the sebaceous gland by lamp radiation. For this
30 purpose, the lamp radiation spectrum has to be filtered so that its filtered part becomes the same as the absorption spectrum of the molecules and particles. For example: organic dye molecules, melanin, carbon, flueren with PDT effect, Au, Cu, Ag particle with

plasma resonance can increase irradiance around particles. The duration of the pulse should be shorter than the time of thermal relaxation of the sebaceous gland which is 50–1000 ms.

The intensity and fluence depend on the concentration and extinction of the molecules or particles but they should not exceed the threshold of epidermis damage or destruction. Therefore, cooling of the epidermis may be used to increase the efficiency of the destruction. For more effective delivery of the absorbing molecules and particles to the sebaceous gland, they may be combined with the lypophil particles. Dye molecules may be represented by the molecules of food dye, dye used for hair coloring and others.

10 The particles may be represented by particles of melanin, carbon (for example, Indian ink), etc. Molecules of fulleren (for example, C₆₀) are among the most effective. These molecules have broad band absorption spectrum in the visible range. The important property of these molecules is the generation of singlet oxygen under photoexcitation. Singlet oxygen may additionally damage the sebocytes and bacteria. The insertion of the

15 absorbing molecules and particles into the sebaceous gland may be done by heating of the skin, phonophoresis, electrophoresis magnetophoresis (if the particles have electric or magnet moment).

Particles inserted into a hair follicle and sebocytes may be used for hair management. In this case the contrast in absorption of the hair follicle with respect to the epidermis may be increased. This makes the treatment of light/gray hair and highly pigmented skin easier and provides more permanent hair loss (i.e. the absorbing particles or the molecules can be easily delivered into the region close to the bulge). The sebaceous gland may also be destroyed by utilizing the selectivity of specific heat of the gland vs. surrounding dermis, this selectivity being due to the high concentration of

25 lipids in the gland. Thus, the gland may be heated by using band(s) of the spectrum with high water/lipid absorption and deep penetration, for example 0.85 – 1.85 μm with cutting/filtering of the strong peak of absorption of water surround 1.4 μm by a 1-3mm water filter and selective cooling of the dermis up to the depth of the sebaceous glands (0.5-1mm).

30 Based on the above, preferable components for the device D shown in Figs. 1, 2 are now considered.

Lamp

The lamp 2 in the device shown in Fig. 1 may be a gas discharge lamp based on the inertial gases Xe, Kr, Ne and others, a metal halide lamp, mercury vapor lamp, high pressure sodium lamp, fluorescent lamp, halogen lamp, incandescent lamp etc. The lamp has a linear tube shape. - Other variations include U shape or ring shape. The dimensions of the lamp are chosen on the basis of the device output parameters. For linear tubular lamps, the optimum shape of the output beam is rectangular $a \times b$. The length of the discharge gap, that is distance l between electrodes, is chosen to be equal or bigger than one of the rectangular dimensions b . The inner diameter of the lamp should be minimized, but be sufficient to provide a given life-time N of the lamp (where N = number of lamp working cycles). Minimum lamp diameter provides the highest efficiency for transport of radiation energy to the skin and minimum losses of light due to absorption in the lamp. Minimum absorption of light inside the lamp increases the efficiency of back-reflected light from the skin. For low pulse repetition rate, the lamp may be cooled by the gas in gap 7, and for high repetition rate and high mean power, by a liquid in gap 7. The lamp tube may contain ions absorbing unwanted spectral components and converting these components into the desired spectral range. The optimum way to accomplish this is for the coating to reflect the unwanted radiation back into the lamp. This increases the efficiency of the lamp in the desired spectral range due to additional absorption of the reflected components in plasma.

Reflector

The reflector 3 may have various shapes (Fig.13). The main conditions providing maximum reflector efficiency are the following:

1. The ratio of the sum of the areas of the reflector's components providing significant reflection to the sum of the areas of the reflector's components which provide little or no reflection must be maximized. To provide this condition, the reflection index for working parts of the reflection must be close to one within the working range of spectrum. The best material for the specular reflector is Ag (visible or IR range) or Al (UV range). The reflector may be coated by a polymer or inorganic coating or the coating may be coated on the inside or outside of tube 4 or on lamp 2. In the later case, foil extending from the tube or other reflecting wings may extend to the waveguide to

minimize photon loss. For a diffuse reflector, BaSO_4 powder may be used. The area of low-reflecting or non-reflection components in planes which are perpendicular to the axis of the lamp should be minimized. If this requirement is satisfied, the design of the device will become simpler and it will be possible to avoid cooling of the reflector.

- 5 2. The geometry of the specular reflector should provide the minimum number of reflections of lamp light from reflector 3 before being coupled into the waveguide. The reason for this is that there is a photon loss of about 5% to 15% per reflection; therefore, the lower the number of reflections, the less the photon losses. One way to reduce the number of reflections is to keep the reflector as small as possible, generally by moving
10 the reflector close to the lamp. Under high color temperature of the lamp ($T > 6000\text{K}$), the total length of the path for the rays going across the lamp discharge gap should also be minimized in order to reduce losses due to absorption inside the lamp. A diffuse reflector has less efficiency than a specular reflector because the number of reflections from the lower reflective surfaces is greater than for the optimum specular reflector and
15 the total length of the light paths inside the lamp is longer. However the diffuse reflector may have high efficiency if the area of low-reflecting components of the reflector is small and the lamp has low color temperature. For these conditions, angular spectrum at the output of the device will be widest. Therefore, this reflector may be used in cases which do not require deep penetration of light into the skin, for example, for skin
20 rejuvenation and for pigmented lesions, but not for deep spider veins. The specular reflector for this device may be imaging or non-imaging. An imaging reflector is advantageous for the concentration of lamp light to a spot of minimum size, especially where the dimensions of the emitting source are small. However, where the dimensions of the emitting source are large, an imaging reflector is disadvantageous because the
25 radiator is placed inside the handpiece. The cost of these reflectors is also high (i.e. they need far better quality reflector components).

Non-imaging reflectors have lower efficiency; however, they are cheaper, have smaller dimensions and could provide more uniform irradiation for large spot size. In table 5, values of efficiency for the different specular reflectors shown in Fig.13 are represented.
30 The dimensions of the lamp are $5 \times 50 \text{ mm}$, the mean absorption in the lamp is 0.1 cm^{-1} ($T_c=6000\text{K}$) and the reflection index of the reflector is 0.94. The distance between the center of the lamp 2 and the waveguide input is $h = 7.5 \text{ mm}$ (excluding reflectors shown

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in 13a, 13c, and 13ℓ. As can be seen from table 5, efficiency for the represented reflectors differ within a 12% range. An increase in efficiency of the reflectors may be achieved by reducing the number of lamp rays which impinge on the reflector surfaces where the electrodes and gaps for lamp cooling are situated. In order to provide this specification, the axial cross-section of the reflector (Fig.14) may be represented as a curved surface (sphere, parabola, ellipse) with its center situated in the center of the lamp or as a trapezoid. However, this increases the cost of construction. A construction which is both simple and effective is the reflector shown in fig. 13a or 13b. In this reflector, the reflecting surface has the shape of a simple cylinder and may be combined with the surface of the lamp envelope or tube 4. In the first case, cooling of the lamp and the reflector may be done outside the reflector, and in the second case, inside the tube. Further, since the electrodes are generally non-reflecting, they can be a major source of photon loss. One option is to use lamps without electrodes which are charged or excited by RF or other suitable techniques. Another option is to use electrodes formed of a material having high reflection.

Waveguide

The waveguide has the following functions in the described device:

1. The optical conjugation between the reflector 3 and the skin 1 (i.e. the transportation of lamp light and reflected light to the skin and back with minimum losses). In other words, an optical system with minimum photon leakage is provided and the waveguide is also a major factor in the increase in skin illumination resulting from the return or recycling of photons.
2. The creation of uniform illumination on the skin surface with fixed spot dimensions.
3. Cooling of the skin for the protection of the epidermis.
4. The pressing of the skin for the increased light transmission and better thermal and optical contact.
5. Laser or superluminescent conversion of the light.
6. Measurement of the index of light reflection from the skin in order to control the power of the light delivered into the skin depending on the properties of the skin.
7. Additional mechanical and electrical isolation of the skin from the lamp in order to increase patient safety.

Waveguide 5 may be in the form of a rectangular prism (Fig.1), cut pyramid (Fig.15), or complex curvature cut pyramid (Fig.16). For a rectangular prism without coatings, the refraction index should satisfy the condition $n > 1.4$, where n is the refractive index of the waveguide, for the transport of the radiation from the lamp to the skin without losses, and $n > 1.7$ for the return of photons reflected from the skin back into the skin. Thus, an air gap should be provided between lamp 2 or tube 4 and waveguide 6. In order to provide uniform illumination on the skin surface and minimum photons loss, the gap between tube 4 and the waveguide should be of minimum size. While point contact between the lamp and waveguide may be possible, potential vibration of the lamp makes this a less desirable option.

In Fig.17, the dependence of the non-uniformity of skin illumination on the length of the waveguide (the dimensions of the lamp 5x50 mm, the transverse dimension of the waveguide 16x46, the refraction index of the waveguide 1.76) is represented. Waveguide 5 may be in the form of a cut right-angle pyramid (Fig.15) or a curved pyramid (Fig.16) prism for increased intensity of the fluence on the skin surface. The curved cut pyramid also allows transformation of the rectangular spot into a symmetric square or circle. The maximum value of the concentration of energy density is achieved if losses in the waveguide are not high and the ratio of the square of the input aperture to the output aperture is maximum.

If the losses in the waveguide are limited to 5%, the maximum concentration (i.e. the ratio of energy density on the skin surface with the cut-off pyramid (Fig.15) to the energy density on the skin surface with the right-angle prism (Fig.1) will be achieved for certain angles of the pyramid defined in two dimensions. For the long axis, this angle is equal to 17° , and for the short axis, is equal to 3.8.

The length of the waveguide is limited by absorption losses of the waveguide and by the dimensions of the handpiece. For a waveguide length $H=60$ mm $A=46$ mm, $B=16$ mm; the maximum concentration of light by a cut-off pyramid in comparison with a right-angle prism is equal to 1.95 for $n_w=1.45$ (quartz) and 2.3 for $n_w=1.76$ (sapphire). A equals the length of the waveguide along the long axis at the light receiving end of the waveguide, and B equals the length along the short axis.

The width of the angular spectrum coupled into the skin by the waveguide depends on the refraction index of the medium placed in the gap between the tube 4 and

the waveguide as well as on the angle of the pyramid. In Fig.17, the angular radiation spectra from the device (Fig.1) in the skin near the surface (ballistic photons) are represented. Curve 47 shows the angular energy distribution of the ballistic photons in the skin for the device (Fig. 1,2) with a sapphire waveguide made as a right-angle prism (A=46 mm, B=16 mm, H=15 mm) and air in the gap between tube 4 and waveguide 5. Curve 48 describes the same situation; however the gap between the tube 4 and waveguide 5 is filled with a transparent substance with a refraction index equal to $n=1.42$. Curve 49 describes the angular distribution of the energy of ballistic photons for the waveguide made as a cut-off quartz pyramid (A=46 mm, B=16 mm, a=11.6 mm, b=28 mm, H=50 mm). From Fig.17, it is seen that it is possible to control the angular spectrum of the photons inside the skin using waveguide 5 and changing the refraction index of the substance placed between the tube and the waveguide. In accordance with well-known theory, changing the angular spectrum of the photons inside the skin is the best way to control the depth of penetration of light into the skin, especially for long waves. In order to achieve an extremely narrow angular spectrum and maximum penetration depth, air should fill the gap between tube 4 and waveguide 5 and the waveguide should be made as a right-angle prism or as "divergent" cut-off pyramid 51 (Fig.15). The surface AxB is faced to the lamp and axb is in contact with the skin. This shape is most suitable for the treatment of deep targets such as hair bulge, hair bulb, dermal/ hypodermal junction, subcutaneous fat, deep veins, etc. In order to provide maximum angular spectrum and minimum depth of light penetration into the skin, the space between the tube and the waveguide should be filled with a substance with a refraction index greater than 1, preferably equal to or greater than the refraction index of the skin, but less than the refraction index of the waveguide. The angular spectrum may be expanded additionally due to application of the waveguide made as a convergent cut-off pyramid 50. A device with high divergence of the radiation in the skin and low penetration depth may be used for pigmented lesions, vascular lesions and skin rejuvenation.

Fig.18 shows a device with the simplest waveguide combined with a reflecting tube providing maximum concentration of energy near the surface of the skin. In this device, waveguide 52 transforms smoothly to perform the function of tube 4, gap 7 being formed between this waveguide and the lamp. Reflector 53 is mounted on, coated on or

otherwise formed on the waveguide. A reflector on the surface of waveguide 52 is necessary. In this embodiment, it is impossible to provide total internal reflection on the waveguide junction due to the wide angular spectrum of the radiation. Reflector 53 may be made as a vacuum or galvanic metal coating (Ag, Cu, Au, Al) on the dielectric waveguide 52 or as a flexible sheet with a reflecting coating. The flow of liquid or gas in gap 7 between the waveguide and the lamp is used for cooling both the waveguide 52 and the lamp 2 (and through the waveguide reflector 53).

An important function of the waveguide is providing uniform distribution of radiation on the skin surface this being a critical parameter for the safety of the epidermis. Uniformity of illumination is provided due to the correct choice of waveguide's length. A typical dependence of radiation distribution intensity non-uniformity on skin surface 54 on the length H of the waveguide is shown in Fig.19. The non-uniformity (unevenness) Z is defined as $Z = (I_{\max} - I_{\min}) / 2(I_{\max} + I_{\min})$, where I_{\max} is maximum and I_{\min} is minimum energy density (power) on the skin surface. For better safety, $Z=0$. From Fig.19, it can be seen that this dependence has a periodic, resonant decreasing character for increasing H. For short waveguides when their length $H \approx B$, the length of the waveguide should be close to the lengths for resonance H_1, H_2, H_3, H_4 . For $H \gg B$, the radiation distribution is uniform independent of the length H of the waveguide.

In order to provide maximum coupling efficiency of lamp radiation into the skin, the front face of waveguide 52 should be in optical contact with skin 1. To provide this, the waveguide is pressed against the skin and all gaps between the waveguide's output plane and skin more than $0.2 \mu\text{m}$ should be filled with a liquid with a refraction index $n > 1.2$. In order to minimize these gaps, it is useful to expand the skin in the contact field. Good optical contact automatically provides good thermal contact between waveguide 5 and skin 1. The pressing of the skin by the waveguide, especially in places near the bone or where there is a hard plate under the skin being treated, for example where there is a hard reflecting plate inserted in the gap between the inner lip and teeth/gum of the patient to prevent absorption of radiation by the patients teeth or fillings therein, and thus heating of the teeth where the patient's lip is being treated, allows considerable increase in the depth of light penetration into the skin. This effect is achieved due to decreased scattering in the skin under pressure and the removal of blood from underlying vessels.

While what has been described above is clearly preferable, there may be applications where adequate optical contact can be obtained with the waveguide very close to, but not necessarily in contact with the skin.

In order to increase pressure on the skin, the front face of the waveguide may be made in the form of a convex surface (Fig.20a). Where treatment of blood vessels is being performed, pressing of the skin should generally be avoided since blood in the vessel is generally the chromophore used for treatment. In this case the face of the waveguide may be made in the form of a concave surface (Fig.20b) or it may have a rim 55 (Fig.20c). Rim 55 or the sharp edges of the waveguide (Fig.20b) can block blood flow in the vessel on either side of the treatment field, resulting in a concentration of non-flowing blood in the treatment field.

The waveguides of, for example Figs.20b and 20c, may also be utilized to control the blood vessel being treated. In particular, there is a concentration of thin, for example 10-30 μ m blood vessels in the plexus which is located just below the dermis epidermis (DE) junction of the skin; below these plexus vessels are thicker, but still relatively thin, spider veins, and below the spider veins are thicker blood vessels. Generally treatment of the plexus vessels is not desired. However, radiation absorption in these vessels can both cause undesired heating of the plexus which then cause blistering and pain, and also absorbs energy, reducing the photons reaching the vessel on which treatment is desired. It is therefore desirable that these plexus vessels be compressed (and/or cool plexus) so as to remove blood therefrom, while not compressing the vessel to be treated. The recess of the waveguide of Fig. 20b or rim 55 (Fig. 20c) can be selected so that the top of the recess presses on the plexus vessels removing blood therefrom, while the edges of the recess only pinch the vessels on which treatment is to be performed, trapping blood therein. A deeper recess in the waveguide/rim would permit blood to, for example, also be removed from spider veins to facilitate treatment of deeper, larger vessels. Thus, by controlling both the depth of the recess in the waveguide/rim and the pressure applied, the depth of the blood vessel being treated may be controlled. Red or blue light, depending on the vessel being treated, may be utilized to detect blood flow in vessels, and thus to provide feedback for controlling the pressure applied by the waveguide to the patient's skin. With the convex waveguide of Fig. 20a, control of pressure alone can be used to control the depth of the blood vessel being treated. This control of the depth of

blood vessels being treated by use of a suitably shaped waveguide is another feature of the invention.

Skin texture improvement may also be achieved by the heating of small vessels in the plexus and superficial papillary dermis to produce an inflammatory reaction in the vessels, resulting in the production of elastin and stimulating fibroblast to grow new collagen. In this case, controlled compression of skin surrounding the treatment zone by rim 55 (Fig. 20c) can significantly increase vasculization of small vessels and increase efficiency of the treatment.

The output edge or face of the waveguide may have spatial non-uniformities. In this case, damage of the skin will be non-uniform. The size of the non-uniform fields may be less than 50 μ m. The non-uniform damage may be useful for skin rejuvenation, or for vascular or pigmented lesions, tattoos, etc., because it decreases the peak of extremely strong damage of the skin: blistering, purpura etc. At the same time, the damaged islands heal quickly because tissue between the damaged islands is not damaged and can therefore provide cell proliferation. In order to provide non-uniform damage of the skin surface, the face of the waveguide may have a modulated profile 56 as is shown in Fig.20d. A spatial mask 58 (Fig.20e) may also be coated (reflected mask) on the front surface of the waveguide, for example a flat mask. Patterned index variations (phase mask) in the waveguide may also be employed. Other optical techniques may also be utilized to accomplish this objective. At least some of the techniques indicated redistribute light to provide selected treatment spots.

Waveguide 5 may be made as a lasing or superluminescent waveguide. In this case, the wave spectrum of the lamp may be actively profiled and the angular spectrum of the lamp may be narrowed in order to provide delivery of the light to greater depths. Waveguide 5 may be partially or entirely made of a material impregnated by ions, atoms or molecules having absorption bands in the range of the lamp radiation and lasing or superluminescence transitions in the desired spectral range. Waveguide surfaces 59 and 60 (Fig. 21a) should be parallel with a high accuracy that provides minimum losses of laser generation (better than 30 minutes, preferably better than 10 seconds) and having a curvature which minimizes diffraction losses. Surfaces 59 and 60 have coatings, the coating on surface 59 having a refraction index which is close to 100% for lasing or superluminescent wavelengths and minimum refraction index for lamp radiation in the

desired spectral range and within the range of the ions, atoms and molecules absorption. The coating on surface 60 has a refraction index of a value which is optimum for laser generation. In order to increase the intensity or fluence of laser generation, waveguide 5 may be made in two parts: active part 61 and passive part 62 (Fig. 21b). Active part 61 is doped and part 62 has no absorptive dopants. The waveguide may consist of several parts 61 and 62 or active parts 61 may be formed by spatially selective doping. High-reflecting coatings 59 and 60 may be made only on the edges of the active part of the waveguide. Additionally, the refraction index of the active part of the waveguide may be greater than the refraction index of the passive part in order to realize the waveguiding effect for laser radiation. The radiation of the lamp propagates along waveguide 5, intersects many times with active parts 61 and excites the active dopants. If the waveguide consists of several parts, the generation takes place in the elements 61 which have less cross-section than the waveguide. Therefore the radiation decreases wave and spatial spectra and increases the fluence. Suitable lasing materials include: $\text{Cr}^{3+}:\text{Al}^{2}\text{O}^{3}$, $\text{Ti}^{3+}:\text{Al}^{2}\text{O}^{3}$, Nd:YAG, SiO_2 :Rodamin 6G and others. Thus, the embodiment of Fig.21b provides treatment with the combination of both a lamp and a laser, the waveguide 61 being a laser which is pumped by lamp 62; the combination is required since if the whole waveguide were formed from a laser, there would not be enough fluence for desired treatment, or in other words, there would not be enough gain. Fig.22 shows the radiation spectrum 63 of the proposed device. In this example, an active waveguide with the elements 61 made of ruby and Nd:YAG is used. This waveguide has coatings 59, 60 providing lasing at wavelengths of 694 nm and 1064 nm. The spectrum 64 of the lamp without waveguide is presented for comparison. Spectrum 63 may be efficient for the treatment of the deep veins.

Filtration of light

Optimum profiled spectrum of the lamp (OPSL) is determined by the treatment target. Optimum conditions are: 1) Temperature of epidermis is lower than temperature of thermal necrosis, 2) Temperature of the target is higher than temperature of thermal necrosis, 3) Loss of light energy in the filter is minimized. Mathematically it has been demonstrated that OPSL requires a sharp cutoff. Fig. 7a-7c show OPSL as a result of calculations following the above conditions: Fig.7a being for mulatto skin/hair removal,

Fig.7b being for white skin/spider vein treatment, and Fig.7c being for skin rejuvenation through collagen heating. Simple criteria for OPSL can involve one or more wavelength bands selected/filtered from a lamp spectrum, the band(s) being selected such that the ratio of temperature rise of the target (hair shaft, matrix, vessel, vein, pigment lesion, tattoo, etc.) to temperature rise of the epidermis is more than certain numbers S . The number S depends on the desired level of safety for the procedure. Higher S gives a higher safety level. To maximize efficiency of the lamp, S should be about 1.

Filtration of the light spectrum can be realized by all the optical components of the proposed apparatus. Possible filtration mechanisms include wavelength selective absorption of light in lamp 2, the liquid in gap 7, tube 4, waveguide 5, filter 6, and the wavelength selective reflection of light at reflector 3. Filter 6 may be implemented as a multilayered dielectric coating, reflecting coating, absorbing medium, or spectral resonant scatterer.

Use of a reflecting coating as a filter is desirable to avoid additional losses of light, excess light heating, and to minimize required cooling. A filter of this kind augments the radiation efficiency of the lamp in the proposed device by the reabsorption of superfluous light in the lamp and the increasing of its light output. However, at large angles of incidence, a dielectric interference filter better transmits the short-wavelength part of the light spectrum to the skin than the long-wavelength part. This leads to additional heating of the epidermis useful for treatment of pigmented and vascular lesions only, provided the vascular lesions are very superficial. Conversely, an absorbing filter better transmits the long-wavelength part of the spectrum than the short-wavelength portion. This is better for the treatment of deeper targets and is safer for the epidermis. Unfortunately, an absorbing filter is heated by light and needs cooling. Therefore, it is most efficient to place this filter on lamp 2 or inside tube 4. If this is the case, liquid or gas in gap 7 cools the filter simultaneously with the lamp, the latter being the major source of heat. The filter may be implemented as absorbing dopes (ions, atoms, molecules, microcrystals) added to the liquid in gap 7 or to the material which lamp 2 or tube 4 is made of. Where water filtering is desired, the fluid in gap 7 may be water, either alone or doped as desired. Other fluids, such as oil, alcohol, etc. could also be used in gap 7.

Moreover, an additional tube 65 (Fig. 23a) may be included inside tube 4, the former being made of absorbing material, for instance glass doped by Ce, Sm, Eu, Cr, Nd, La, Fe, Mg, Tm, Ho, Er, etc, ions or by semiconductor microcrystals. The tube may be replaced by particles or slabs, fibers or other components 66 of the same material (Fig. 23b)

5 embedded into the cavity between lamp 2 and tube 4. Tube 65 and components 66 are cooled, the latter being an advantage because of the strong filtration and high average power of the apparatus proposed. The filtration may be implemented by using resonant scattering with respect to the indices of refraction. For instance, let the refraction index of particles 66 be chosen to coincide with that of the cooling liquid at wavelength λ .

10 Then, there exists no scattering in the tube at wavelength and, therefore, the transmission is a maximum. As the wavelength is detuned from λ , the mismatch of refraction indices grows, reinforcing both the scattering and extinction of light. If the refractive index of at least one of the components 7 or 66 changes as a function of the power of the light or of temperature this scattering medium can automatically (self) regulate fluence on the

15 tissue. For example, for low power, the difference in refractive indexes Δn between 7 and 66 is minimum and attenuation of the light due to scattering is also minimum. But for high power, due to the non linearity of refractive indexes of 7 or (and) 66, Δn increases and attenuation of light increases too. This mechanism can be used for protection of skin from high fluences. Filter 6 may be implemented using the same principle. In this case,

20 the spectrum of transmittance may be controlled, for instance by an electric field, provided one of the scattering components exhibits a strong dependence on an electric field, for example liquid crystal or segnetoelectrical ceramics. The filter 6 can be made as a suspension of liquid (water as example) and solid state particles with matching refractive indexes $\Delta n \approx 0$ when the liquid is frozen (ice). Scattering and attenuation of light in this

25 condition is very low. The temperature of waveguide 5 (around 0°C) will remain as melting temperature of filter 6 until the liquid is completely melted. This period of time can be used for treatment of skin with good cooling. Refractive indexes of medium in liquid and crystal conditions are very different. So, after melting, the liquid 6 is going to be a high scattering plate with significant attenuation of the beam. When 6 loses its cooling

30 capability, the fluence on the tissue will thus automatically drop to prevent tissue from damage.

To filter the light spectrum near the IR absorption peaks of water at 1.4 and 1.9 μm , a liquid water filter with a thickness of 1 – 3 mm may be used, which water may also be used for cooling.

5 Cooling

To increase the light energy deposited to the skin, the skin, may be selectively cooled. Cooling of skin to temperatures below 4 $^{\circ}\text{C}$ may be effective for reducing or eliminating pain. In the apparatus proposed, skin cooling is implemented through contact with the cooled tip of waveguide 5. Several mechanisms for cooling waveguide 5 are possible.

- 10 Fig. 24 shows a cooling mechanism for waveguide 5 which is most effective for large A and B dimensions and significant heat flux from the skin (highly pigmented skin, long pulses). The waveguide of a material having good thermal conduction properties, such as sapphire, has a plurality of cuts 67 formed therethrough, with cooling liquid or gas circulating through the cuts. The cuts may have circular, rectangular or other cross-
- 15 section. The inside surface of the cuts should exceed in total area that of the waveguide tip contacting the skin. The cuts are distributed uniformly over the waveguide, thereby eliminating temperature gradients or at least decreasing the gradients from what they would be if only the sides are cooled. The cooling may also be accomplished through evaporation of a liquid like freon from the cut surfaces. Fig. 25 shows a cooling
- 20 mechanism in a composite waveguide assembled of a part 69 which may be of a poor heat-conducting material and a plate 70 of a highly heat-conducting material, cooling liquid or gas 68 circulating in and filling the thin gap between them. Furthermore, light-volatile liquid (for example evaporating spray as R134A) may be injected into the gap between 69 and 70. The mechanism of Fig. 25 also provides uniform cooling of skin for
- 25 a large waveguide. Fig. 26 shows a cooling mechanism for the side surface of the waveguide, making use of circulating fluid, gas, or spray. The mechanism includes components 71 removing heat from the side surface of waveguide 5. Component 71 may be circulating cooling fluid or may be a Peltier or other thermoelectric component. This mechanism is applicable provided at least one dimension A, B is small enough.
- 30 Additional plates 72 cooled by the same cooling components 71 may be provided, plates 72 being used to pre- and postcool the skin when the apparatus is scanned over the skin surface.

Fig. 27 shows composite waveguide 69, 70 cooled by a spray 73 of a fluid with a low evaporation temperature like freon. Reservoir 76 containing the liquefied fluid is connected through tube 75 to a valve 77 controlled by an electrical or mechanical mechanism 74. When valve 77 is opened, the liquefied gas is piped under pressure from reservoir 76 to tube 71 and is then sprayed through nozzle 72. The pulse duration while the valve is open is chosen to pipe enough fluid to component 70 to cool it to the prescribed temperature. This temperature, and the thickness of element 70, are chosen to cool the skin to the prescribed depth, preventing epidermal injury. Tube 71 preferably includes a contact sensor so that valve 77 is operated when tube 71 contacts the skin. It is seen that this occurs before element or plate 70 contacts the skin. This results in the cryogen or other cooling spray being applied both to the skin and to plate 70, resulting in a precooling of the skin and, when plate 70 comes into contact with the skin also in parallel cooling. The thickness of plate 70 can control the depth of cooling

Component 70 may be made of sapphire or diamond; the material of waveguide 69 has to be heat insulated in part from waveguide 70 through at least one of its low heat conductivity and low heat capacity (for instance, plexiglass or glass) or by means of glue.

The advantage of the mechanism of Fig. 27 is that it prevents the overcooling of the epidermis for properly chosen thickness of plate 70 even though the initial temperature of plate 70 is low. Furthermore, the unavoidable (when not using sprays) temperature gradients smooth out when the fluid is sprayed onto plate 70. The fluid is sprayed before waveguide 70 touches the skin. Plate or waveguide 70 may be placed very close to the skin surface and, therefore, the sprayed fluid precools the waveguide and the skin simultaneously. Then, both optical and thermal contact between the skin and the waveguide are established, an optional time delay is introduced, and light from the lamp then irradiates the skin. Numeric simulations show that freon boiling at temperature -26°C cools the epidermis effectively, provided the sapphire plate thickness 1 is 0.5 – 3 mm. The precooling duration is 0.2 – 1 s. For all the processes to be synchronized, the mechanism of opening valve 77 is preferably controlled from a skin touching sensor, for example a sensor in tube 71.

For optical dermatology apparatus where a cooling fluid, for example water or air, is flowed over a contact plate 70, the thickness of this plate may also be selected to control the depth of cooling as for the plate 70 of Fig. 27.

5 Additional Safety Measures

The device of this invention is not only intended for using by a physician, but also for salons, barber shops and possibly home use. For this above reason, one version is supplied with a system for detecting contact with the skin. The system prevents light irradiation of the human's eye and may also evaluate the pigmentation of a patient's skin.

10 The latter capability, in particular, provides a capability to automatically determine the safest irradiation parameters for a particular patient. An embodiment of such detection system is shown in Fig. 28. Light from arc lamp 2 or additional light source 82 (microlamp, waveguide) is directed to the outlet of waveguide 5. Optical fiber 79 is coupled to waveguide 5 by for instance prism 78. Angle α is chosen to minimize or
15 prevent light from lamp 2 or light source 82 from passing through prism 78 so that ideally only light (photons) reflected from skin 1 reach detector 81. Ranges for the angle

α fall within the following limits: $\arcsin\left(\frac{1}{n_w}\right) < \alpha < 90^\circ$. For sapphire

$34.6^\circ < \alpha < 90^\circ$. On touching the skin, backscattered light from the skin enters waveguide 78. Within the waveguide, the backscattered light has a broader angle
20 spectrum than the direct light from 2 or 82. The former light propagates within the angle

range $\arcsin\left(\frac{n_{\text{skin}}}{n_w}\right) < \alpha < 90^\circ$. For sapphire this yields $53.8^\circ < \alpha < 90^\circ$. Therefore, if the

condition $\arcsin\left(\frac{1}{n_w}\right) < \alpha < \arcsin\left(\frac{n_{\text{skin}}}{n_w}\right)$ holds, and the angular aperture of the

waveguide is within this angle range, then no light other than backscattered light from the skin enters waveguide 78. The intensity of this light depends on the skin type,
25 especially within a preferable spectral range $600 \text{ nm} < \lambda < 800 \text{ nm}$. The reflected signal is measured by photodetector 81 through filter 80 which cuts off undesirable wavelengths. The output from photodetector 81 is utilized by the system to control power supply 10 (Fig. 2). The minimal signal level reached for perfect optical contact of the waveguide

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with the skin is preset based on the diffuse reflection coefficient for the patient skin type. Contact detection is facilitated by the fact that the signal applied to detector 81 jumps significantly on contact. Filter 80 assures this occurs only for the reflected light. The optical system of Fig. 27 protects the skin from injury caused by variations in skin parameters, for instance by inhomogeneous pigmentation. Photodetector 81 may be connected directly to waveguide 5. Moreover, the apparatus is also capable of being controlled based on measurements of the irradiance inside the optical system undergoing minimal photon leakage. This irradiance is proportional to the output energy of the lamp if the lamp is emitting in air or to a standard reflector. But this irradiance proportional to the reflection from the skin if the lamp is emitting in skin. In the latter case, the optical system works like an integrating sphere.

While the invention has been described above with respect to multiple embodiments, and many variations have been discussed, these descriptions are for purposes of illustration only, and further variations may be made therein by ones skilled in the art while still remaining within the spirit and scope of the invention which is to be defined only by the appended claims. For example, while the concepts discussed above have been used in a lamp based implementation, many of these concepts are not limited to use only in a system using a lamp as the radiation source, or even to the use of a non-coherent radiation source.

20

What is claimed is:

All wavelengths in the following tables are determined with tolerance $\pm 5\%$. For example: $0.51\mu\text{m}$ means $0.485\text{--}0.536\mu\text{m}$

Table 1.
Characteristics of flashlamp radiation for hair removal.

Skin type	Color Temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (Treatment of bulb, after filtering)	Fluence, J/cm ² (Treatment of bulge, after filtering)	Beam width, mm (Treatment of bulb)	Beam width, mm (Treatment of bulge)	Cooling temperature, °C
		Thickness of water filter, mm	Short cut off wavelengths, μm						
I – II	4000 - 7000	0 - 5	0.51-0.6	1 - 1000	1-40	5-100	>15	>8	-5-36 (0.1 - 1sec)
III – IV	3000 - 6000	0 - 5	0.5-0.7	1-1000	1-40	5-100	>15	>8	-5-36 (0.1 - 2sec)
V - VI	3000 - 5000	0 - 5	0.6-0.8	1-1000	1-20	5-50	>15	>8	-5-30 (1 - 2sec)

Table 2.
Characteristics of flashlamp radiation for small superficial vascular treatment, and treatment of superficial blood vessels for texture/wrinkle improvement

Skin type	Color Temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (after filtering)	Beam width, mm	Cooling temperature, °C
		Thickness of water filter, mm	Bands of wavelengths, μm				
I - IV	5000 - 10000	0-3	1. 0.38-0.47 2. 0.38-0.6 3. 0.38-0.47&0.51-0.6 4. 0.51-0.6 5. 0.38-0.6&0.75-1.3	0.1-50	0.5-50	>3 or island spots	-5-36 (0.1 - 0.3 sec)
V - VI	5000 - 7000	0-3	1. 0.51-0.6 2. 0.51-0.6&0.75-1.3 3. 0.75-1.3	0.1-100	0.4-20	>3 or island spots	-5-10 (0.1-0.3sec)

Table 3.
Characteristics of flashlamp radiation for deep vein treatment (diameter 0.2-0.5 mm; depth 0.5- 1 mm).

Skin type	Color Temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (After filtering)	Beam width, mm	Cooling temperature, °C
		Thickness of water filter, mm	Bands of wavelengths, μm				
I – IV	4000 - 10000	0-3	1. 0.51-0.6 2. 0.51-0.6&0.75-1.3	5-1000	2-100	>5 or island spots	-5-36 (0.1 - 1sec)
V - VI	3000 - 6000	0-3	1. 0.51-0.6&0.75-1.3 2. 0.75-1.3	5-2000	10 - 100	>5 or island spots	-5-20 (1- 2sec)

Table 4
Characteristics of flashlamp radiation for large leg vein treatment

Skin type	Color temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (after filtering)	Beam width, mm	Cooling temperature, °C
		Thickness of water filter, mm	Bands of wavelengths, μm				
I – VI	2500-5000	0-1	0.75-1.3	100-3000	20-200	>5 or matrix of island spots	-5-10(1-10sec)

Table 5
Characteristics of flashlamp radiation for pigment lesion treatment

Skin type	Color temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (after filtering)	Beam width, mm	Cooling temperature, °C
		Thickness of water filter, mm	Bands of wavelengths, μm				
I – IV	5000-10000	0-3	1. 0.36-1.3 2. 0.5-1.3 3. 0.6-1.3 4. 0.36-0.6 5. 0.5-0.6	0.05-500	1-100	>1 or island of spots	-5-36 (0.3-10sec)

Table 6
Characteristics of flashlamp radiation for dermis treatment for wrinkle improvement

Skin type	Color temperature of lamp, °K	Light spectrum		Pulsewidth, ms	Fluence, J/cm ² (after filtering)	Beam width, mm	Cooling temperature, °C
		Thickness of water filter, mm	Bands of wavelengths, μm				
I – VI	2500-5000	0.1-3	1.0.85-1.85	10-2000	20-200	>3 or matrix of island spots	-5-10(0.3-1sec)
			2. 0.85-1.85&2.1-2.3				

CLAIMS

1. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:
 - a waveguide adapted to be in optical contact with the patients skin; and
 - 5 a mechanism for directing photons from said lamp through said waveguide to the patient's skin, said mechanism including a submechanism which inhibits the loss of photon from said apparatus.
2. An apparatus as claimed in claim 1 wherein said mechanism includes a reflector,
10 said submechanism including said reflector and waveguide being sized and shaped so that they fit together with substantially no gap therebetween.
3. An apparatus as claimed in claim 2 including a reflective material substantially sealing any gap between said reflector and waveguide.
- 15 4. An apparatus as claimed in claim 1 wherein said mechanism includes a reflector, said reflector being sized and mounted with respect to said lamp so as to minimize the number of reflections for each photon on said reflector.
- 20 5. An apparatus as claimed in claim 4 wherein said reflector is small enough and mounted close enough to said lamp to achieve said minimum number of reflections.
6. An apparatus as claimed in claim 4 wherein said reflector is formed on an outer surface of said lamp.
- 25 7. An apparatus as claimed in claim 4 including a tube surrounding said lamp, there being a gap between said lamp and tube through which a fluid is flowed to cool the lamp.
8. An apparatus as claimed in claim 7 wherein said reflector is formed on one of an
30 inner and outer surface of said tube.

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9. An apparatus as claimed in claim 4 wherein said reflector has a substantially cylindrical shape.

10. An apparatus as claimed in claim 4 wherein said reflector is a scattering reflector.

5

11. An apparatus as claimed in claim 10 including a mechanism for controlling the wavelengths filtered by said scattering reflector.

12. An apparatus as claimed in claim 4 wherein said reflector is of a material which
10 filters selected wavelengths of light from said lamp impinging thereon.

13. An apparatus as claimed in claim 1 wherein said mechanism includes a reflector, wherein there is a gap between said reflector and said waveguide, and including a second reflector in said gap which in conjunction with said reflector directs substantially all
15 photons from said lamp to said waveguide.

14. An apparatus as claimed in claim 1 including a mechanism for selectively filtering light from said lamp to achieve a desired wavelength spectrum, said mechanism for selectively filtering being included as part of at least one of said lamp, a coating
20 formed on said lamp, a tube surrounding said lamp, a filter device in a gap between said lamp and said tube, a reflector for light from said lamp, the waveguide, and a filter device between said lamp and said waveguide.

15. An apparatus as claimed in claim 14 wherein said mechanism for selectively
25 filtering is included as part of a plurality of the components listed in claim 14.

16. An apparatus as claimed in claim 14 wherein said mechanism for selectively filtering is at least one of an absorption filter, a selectively reflecting filter, and a spectral resonant scatterer.

30

17. An apparatus as claimed in claim 14 wherein said mechanism includes a multilayer coating.

18. An apparatus as claimed in claim 1 wherein said waveguide is of a length selected to enhance uniformity of the light output from said lamp.

5 19. An apparatus as claimed in claim 18 wherein the uniformity of light output from said waveguide has resonances as a function of waveguide length, and wherein the length of said waveguide is equal to one of the resonant lengths.

10 20. An apparatus as claimed in claim 18 wherein said waveguide has a width and depth at an end of the waveguide adjacent the lamp, and wherein the length of the waveguide is much greater than the smaller of said width and depth.

21. An apparatus as claimed in claim 1 including a mechanism for controlling the angular spectrum of photons within the patients skin.

15

22. An apparatus as claimed in claim 21 including a gap between the lamp and said waveguide which gap is filled with a substance having a selected index of refraction.

23. An apparatus as claimed in claim 22 wherein the length of said gap is minimized.

20

24. An apparatus as claimed in claim 22 wherein said gap is filled with air.

25. An apparatus as claimed in claim 1 wherein said waveguide has a larger area at a light receiving surface than at a light output surface, and wherein said waveguide has curved sides between said surfaces.

25

26. An apparatus as claimed in claim 1 wherein said waveguide has a plurality of cuts formed therethrough, said cuts being adapted to have a coolant fluid flow therethrough.

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27. An apparatus as claimed in claim 1 wherein said waveguide has a surface in contact with the patients skin which is patterned to control the delivery of photons to the patient's skin.

5 28. An apparatus as claimed in claim 1 wherein said waveguide has a surface in contact with the patient's skin which is concave.

29. An apparatus as claimed in claim 28 where said waveguide has one of a concave skin contacting surface and a rim surrounding the waveguide with a concave edge.

10

30. An apparatus as claimed in claim 28 wherein the depth of said concave surface is selected to, in conjunction with pressure applied to the apparatus, control the depth of blood vessels treated by the apparatus.

15 31. An apparatus as claimed in claim 30 including a mechanism for detecting the depth of blood vessels in which blood flow is restricted by application of said concave surface under pressure to the patient's skin, said mechanism permitting pressure to be controlled to permit treatment of vessels at a desired depth.

20 32. An apparatus as claimed in claim 1 wherein said waveguide has a skin contacting surface shaped to permit the application of selective pressure to the patient's skin and to thereby control the depth at which treatment is performed.

33. An apparatus as claimed in claim 32 wherein said apparatus is being used to treat
25 blood vessels, and including a mechanism for detecting the depth of blood vessels in which blood flow is restricted by application of said surface under pressure to the patient's skin and to thereby control the depth at which treatment is performed.

34. An apparatus as claimed in claim 1 wherein said waveguide is at least in part one
30 of a lasing and a superluminescent waveguide.

35. An apparatus as claimed in claim 34 wherein said waveguide includes a lasing waveguide inside an optical waveguide.

36. An apparatus as claimed in claim 1 wherein said waveguide has a skin contacting surface, and including a mechanism which delivers a cooling spray to both the patient's skin and said skin contacting surface just prior to said surface making contact with the skin.

37. An apparatus as claimed in claim 36 wherein said waveguide includes a lower portion adjacent the patient's skin of a material which is a good conductor of heat and an upper portion of a material which is not a good conductor of heat, the thickness of said lower portion controlling the depth of cooling in the patient's skin.

38. An apparatus as claimed in claim 36 wherein said mechanism includes a detector indicating when the apparatus is within a predetermined distance of the patient's skin, said cooling spray being activated in response to said detector.

39. An apparatus as claimed in claim 1 including a rearward facing light output channel from said waveguide which leads to a backscatter detector, said channel being at an angle α to a perpendicular to the skin which assures that only backscattered light reaches the detector.

40. An apparatus as claimed in claim 1 wherein said lamp is driven with a power profile which is one of the power profiles 44, 45 and 46 of Fig. 11.

41. An apparatus as claimed in claim 1 wherein said waveguide is formed as a unitary component with said lamp passing through an opening formed therein.

42. A method for utilizing a lamp for performing hair removal utilizing the parameters of table 1.

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43. A method for utilizing a lamp for performing treatment of vascular lesions utilizing the parameters of table 2, 3 and 4.

44. A method for utilizing a lamp for performing skin rejuvenation utilizing the parameters of tables 2 and 6.

45. A method for utilizing a lamp for performing treatment of acne by at least one of killing bacteria, thermolysis of the sebaceous gland and killing spider veins feeding the sebaceous gland.

10

46. A method of utilizing a lamp for performing treatment of pigmented lesions utilizing the parameters of table 5.

47. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:

15

a waveguide adapted to be in optical contact with the patients skin; and

a mechanism for directing photons from said lamp through said waveguide to the patient's skin, said mechanism including a reflector, said reflector being mounted close enough to said lamp and being small enough so as to minimize the number of reflections for each photon on said reflector.

20

48. An apparatus as claimed in claim 47 wherein said reflector is formed on an outer surface of said lamp.

49. An apparatus as claimed in claim 47 including a tube surrounding said lamp, there being a gap between said lamp and tube through which a fluid is flowed to cool the lamp.

25

50. An apparatus as claimed in claim 49 wherein said reflector is formed on one of an inside and an outside surface of said tube.

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51. An apparatus as claimed in claim 47 wherein said reflector has a substantially cylindrical shape.

52. An apparatus as claimed in claim 47 wherein said reflector is a scattering
5 reflector.

53. An apparatus as claimed in claim 52 including a mechanism for controlling the wavelengths filtered by said scattering reflector.

10 54. An apparatus as claimed in claim 47 wherein said reflector is of a material which filters selected wavelengths of light from said lamp impinging thereon.

55. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:

15 a waveguide adapted to be in optical contact with the patients skin;
a mechanism for directing photons from said lamp through said waveguide to the patient's skin; and
a mechanism for selectively filtering light from said lamp to achieve a desired wavelength spectrum, said mechanism for selectively filtering being included as part of
20 at least one of said lamp, a coating formed on said lamp, a tube surrounding said lamp, a filter device in a gap between said lamp and said tube, a reflector for light from said lamp, the waveguide, and a filter device between said lamp and said waveguide.

56. An apparatus as claimed in claim 55 wherein said mechanism for selectively
25 filtering is included as part of a plurality of the components listed in claim 53.

57. An apparatus as claimed in claim 55 wherein said mechanism for selectively filtering is at least one of an absorption filter, a selectively reflecting filter, and a spectral resonant scatterer.

30

58. An apparatus as claimed in claim 55 wherein said mechanism includes a multilayer coating.

59. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

a waveguide adapted to be in optical contact with the patients skin; and

5 a mechanism for directing photons from said source through said waveguide to the patient's skin, said waveguide being of a length selected enhance uniformity of the optical output from said apparatus.

60. An apparatus as claimed in claim 59 wherein the uniformity of optical output
10 from said waveguide has resonances as a function of waveguide length, and wherein the length of said waveguide is equal to one of the resonant lengths.

61. An apparatus as claimed in claim 59 wherein said waveguide has a width and depth at an end of the waveguide adjacent the source, and wherein the length of the
15 waveguide is much greater then the smaller of said width and depth.

62. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:

a waveguide adapted to be in optical contact with the patients skin;

20 a mechanism for directing photons from said lamp through said waveguide to the patient's skin; and

a gap between the lamp and said waveguide which gap is filled with a substance having an index of refraction so as to selectively control the angular spectrum of photons within the patient's skin.

25

63. An apparatus as claimed in claim 62 including a tube spaced from and substantially surrounding said lamp, and wherein said gap is between said tube and said waveguide.

30 64. An apparatus as claimed in claim 62 wherein the length of said gap is minimized.

65. An apparatus as claimed in claim 62 wherein said gap is filled with air.

66. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

- a waveguide adapted to be in optical contact with the patients skin, said
- 5 waveguide having a larger area at a radiation receiving surface then at a radiation output surface, and wherein said waveguide has curved sides between said surfaces; and
- a mechanism for directing photons from said source through said waveguide to the patient's skin.

10 67. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

- a waveguide adapted to be in optical contact with the patients skin, said
- waveguide having a larger area at a radiation receiving surface then at a radiation output surface and having side walls between said surfaces;
- 15 a reflector on each of said walls to inhibit photon leakage through said walls; and
- a mechanism for directing photons from said source through said waveguide to the patient's skin.

68. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

- 20 a waveguide adapted to be in optical contact with the patients skin, said
- waveguide having a plurality of cuts formed therethrough, said cuts being adapted to have a coolant fluid flow therethrough; and
- a mechanism for directing photons from said source through said waveguide to
- 25 the patient's skin.

69. An apparatus utilizing an optical radiation source to perform optical dermatology on a patient's skin, said apparatus including:

- a waveguide adapted to be in contact with the patients skin, said waveguide
- 30 having a surface in contact with the patients skin which is patterned to control the delivery of photons to the patient's skin; and

a mechanism for directing photons from said source through said waveguide to the patient's skin.

70. An apparatus utilizing an optical radiation source for treatment of a patient's skin,
5 said apparatus including:

a waveguide adapted to be in optical contact with the patients skin, said waveguide having a surface in contact with the patient's skin which is concave; and
a mechanism for directing photons from said source through said waveguide to the patient's skin.

10

71. An apparatus as claimed in claim 70 where said waveguide has one of a concave skin contacting surface and a rim surrounding the waveguide with a concave edge.

72. An apparatus as claimed in claim 70 wherein the depth of said concave surface is
15 selected to, in conjunction with pressure applied to the apparatus, control the depth of blood vessels treated by the apparatus.

73. An apparatus as claimed in claim 72 including a mechanism for detecting the depth of blood vessels in which blood flow is restricted by application of said concave
20 surface under pressure to the patient's skin, said mechanism permitting pressure to be controlled to permit treatment of vessels at a desired depth.

74. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

25 a waveguide adapted to be in optical contact with the patients skin, said waveguide having a skin contacting surface which is adapted for application of selective pressure to the skin to control the depth of treatment; and

a mechanism for directing photons from said source through said waveguide to the patient's skin.

30

75. An apparatus as claimed in claim 74 wherein said apparatus is being used to treat blood vessels, and including a mechanism for detecting the depth of blood vessels in

-55-

which blood flow is restricted by application of said surface under pressure to the patient's skin, said mechanism permitting pressure to be controlled to permit treatment of vessels at a desired depth.

5 76. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

a waveguide adapted to be in optical contact with the patients skin, said waveguide being at least in part one of a lasing and a superluminescent waveguide; and

10 a mechanism for directing photons from said source through said waveguide to the patient's skin.

77. An apparatus as claimed in claim 76 wherein said waveguide includes a lasing material with mirrors on the end inside an optical waveguide.

15 78. An apparatus for utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

a waveguide adapted to be in optical contact with a patient's skin;

at least one of a lasing and a superluminescent material surrounding said lamp;

20 and a mechanism for directing photons from said source through said waveguide to the patient's skin.

79. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:

25 a waveguide having a skin contacting surface adapted to be in contact with the patients skin;

a mechanism for directing photons from said lamp through said waveguide to the patient's skin; and

a mechanism which delivers a cooling spray to both the patient's skin and said skin contacting surface just prior to said surface making contact with the skin.

30

80. An apparatus as claimed in claim 79 wherein said waveguide includes a lower portion adjacent the patient's skin of a material which is a good conductor of heat and an

upper portion of a material which is not a good conductor of heat, the thickness of said lower portion controlling the depth of cooling in the patient's skin.

81. An apparatus as claimed in claim 79 wherein said mechanism includes a detector
5 indicating when the apparatus is within a predetermined distance of the patient's skin, said cooling spray being activated in response to said detector.

82. An apparatus utilizing an optical radiation source for treatment of a patient's skin, said apparatus including:
10 a waveguide adapted to be in optical contact with the patients skin;
a mechanism for directing photons from said lamp through said waveguide to the patient's skin; and
a rearward facing light output channel from said waveguide which leads to a backscatter detector, said channel being at an angle α to a perpendicular to the skin
15 which assures that only backscattered light reaches the detector.

83. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:
a waveguide adapted to be in optical contact with the patients skin;
20 a mechanism for directing photons from said lamp through said waveguide to the patient's skin; and
a lamp driver which drives said lamp with a power profile which is one of the power profiles 44, 45 and 46 of Fig. 11.

25 84. An apparatus utilizing a lamp for treatment of a patient's skin, said apparatus including:
a waveguide adapted to be in optical contact with the patients skin, said waveguide being formed as a unitary component with said lamp passing through an opening formed therein, said waveguide including a mechanism for directing photons
30 from said lamp through said waveguide to the patient's skin.

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85. A method of using optical radiation to treat a patient's skin, said method including:

applying optical radiation from an optical radiation source through a plate having a first surface in contact with the patient's skin to the skin; and

5 applying a cooling fluid to a surface of the plate opposite said first surface; the thickness of said plate being selected to control the depth in the patient's skin to which cooling occurs.

86. A method of using optical radiation to treat blood vessels in a patient's skin, the method including:

10 applying optical radiation from an optical radiation source through a waveguide to the patient's skin, the waveguide having a selectively shaped skin-contacting surface; and

15 applying a selected pressure to the waveguide, the pressure being sufficient in conjunction with the shape of the waveguide, to substantially remove blood from all blood vessels above vessels on which treatment is to be performed.

87. A method as claimed in claim 86 wherein said waveguide has a concave skin-contacting surface, the depth of the concave surface, in conjunction with the applied pressure controlling the depth of blood vessels being treated.

88. An apparatus for utilizing optical radiation to treat a patient's skin, the apparatus including:

a source of optical radiation; and

25 a waveguide through which radiation from the source is applied to the patient's skin, the waveguide having scattering properties which are a function of the temperature of the waveguide, whereby the waveguide may automatically control radiation applied to the patient's skin to compensate for changes in patient skin temperature.

89. Apparatus for utilizing an optical radiation from a lamp to treat a patient's skin, the apparatus including:

a mechanism for applying radiation from the lamp to the patient's skin; and

-58-

a filtering mechanism which prevent all but at least one band of radiation from the lamp to reach the patients skin, said at least one band being selected such that the temperature at a desired target in the patient's skin to the temperature of the patient's epidermis has a selected value.

5

90. Apparatus as claimed in claim 89 wherein said selected value is greater than one.

91. Apparatus as claimed in claim 89 wherein there are a plurality of bands passed by said filtering mechanism.

10

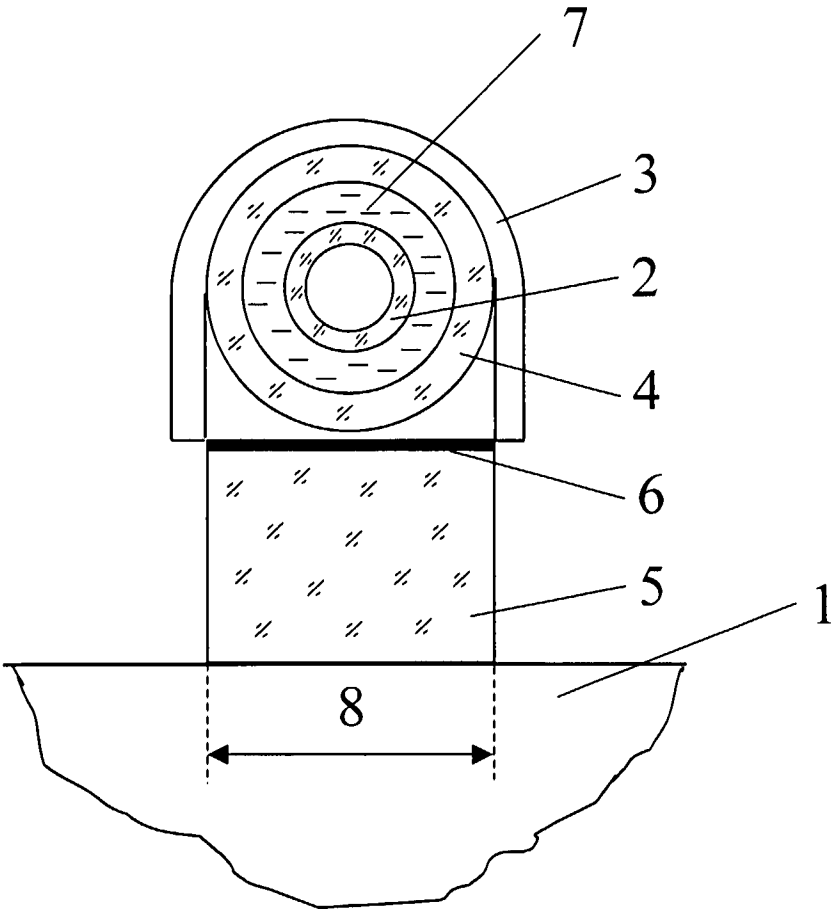


Fig. 1

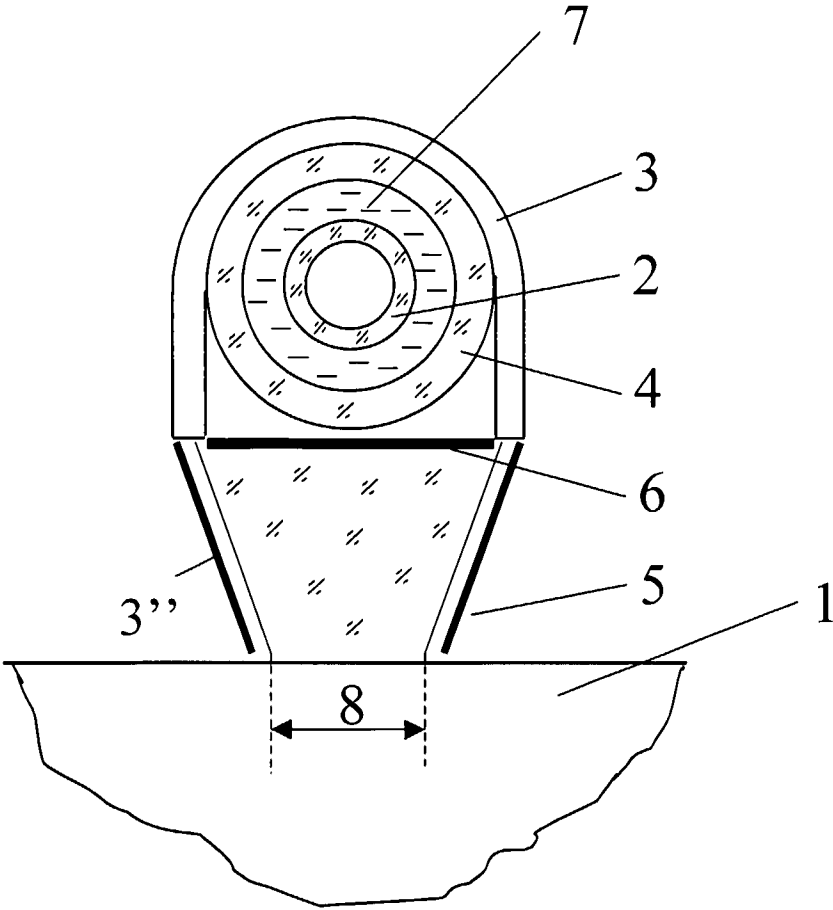


Fig. 1a

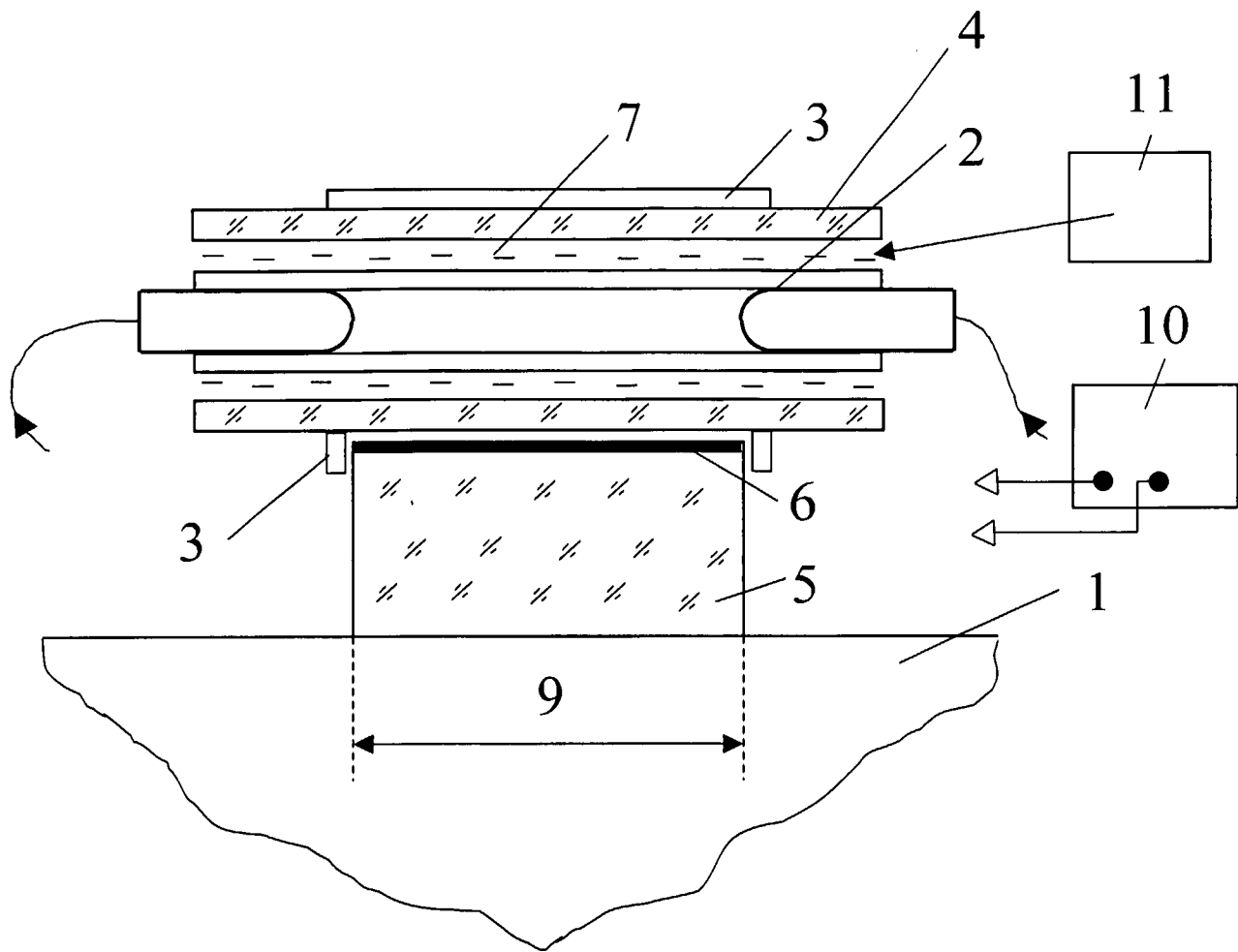


Fig. 2

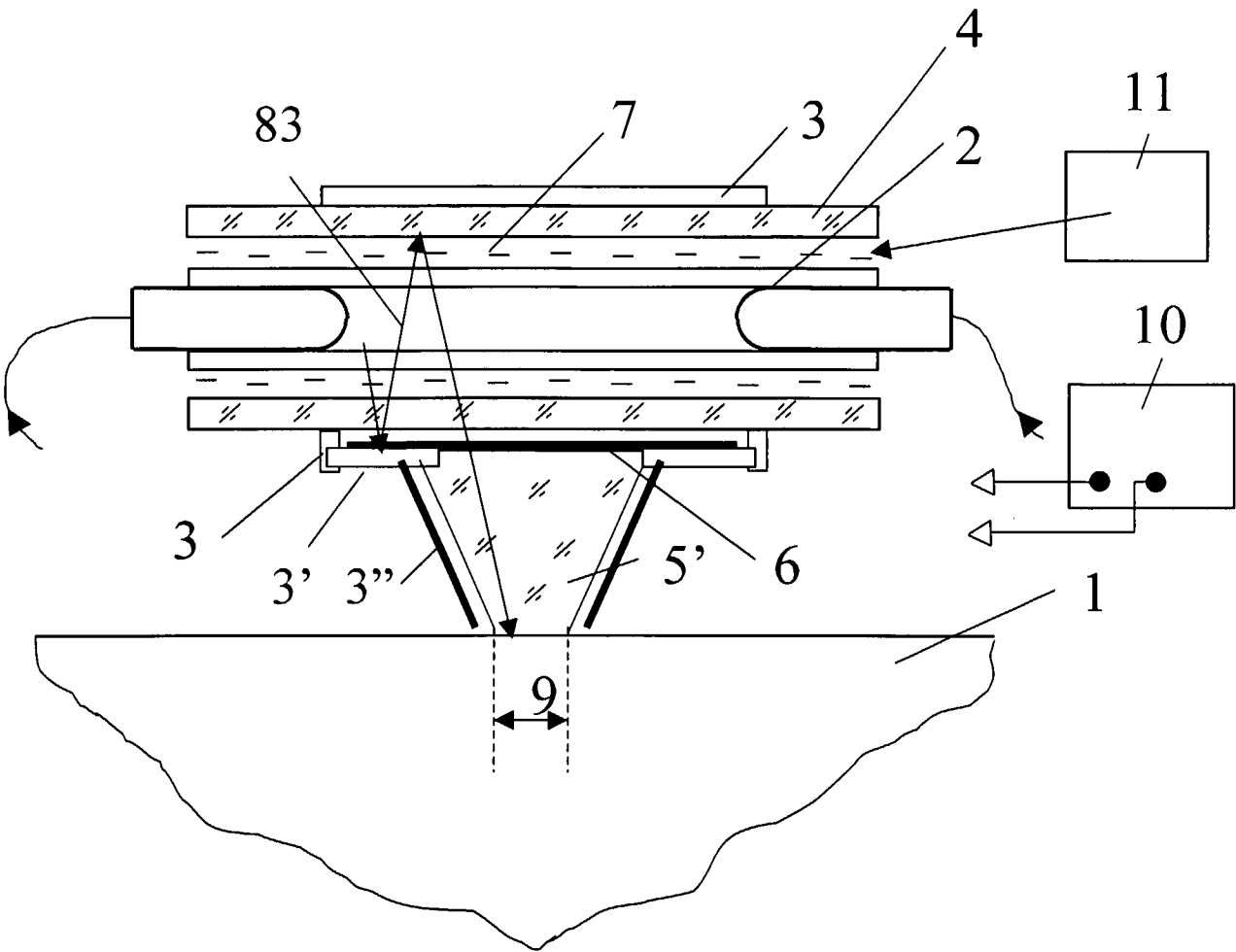


Fig. 2a

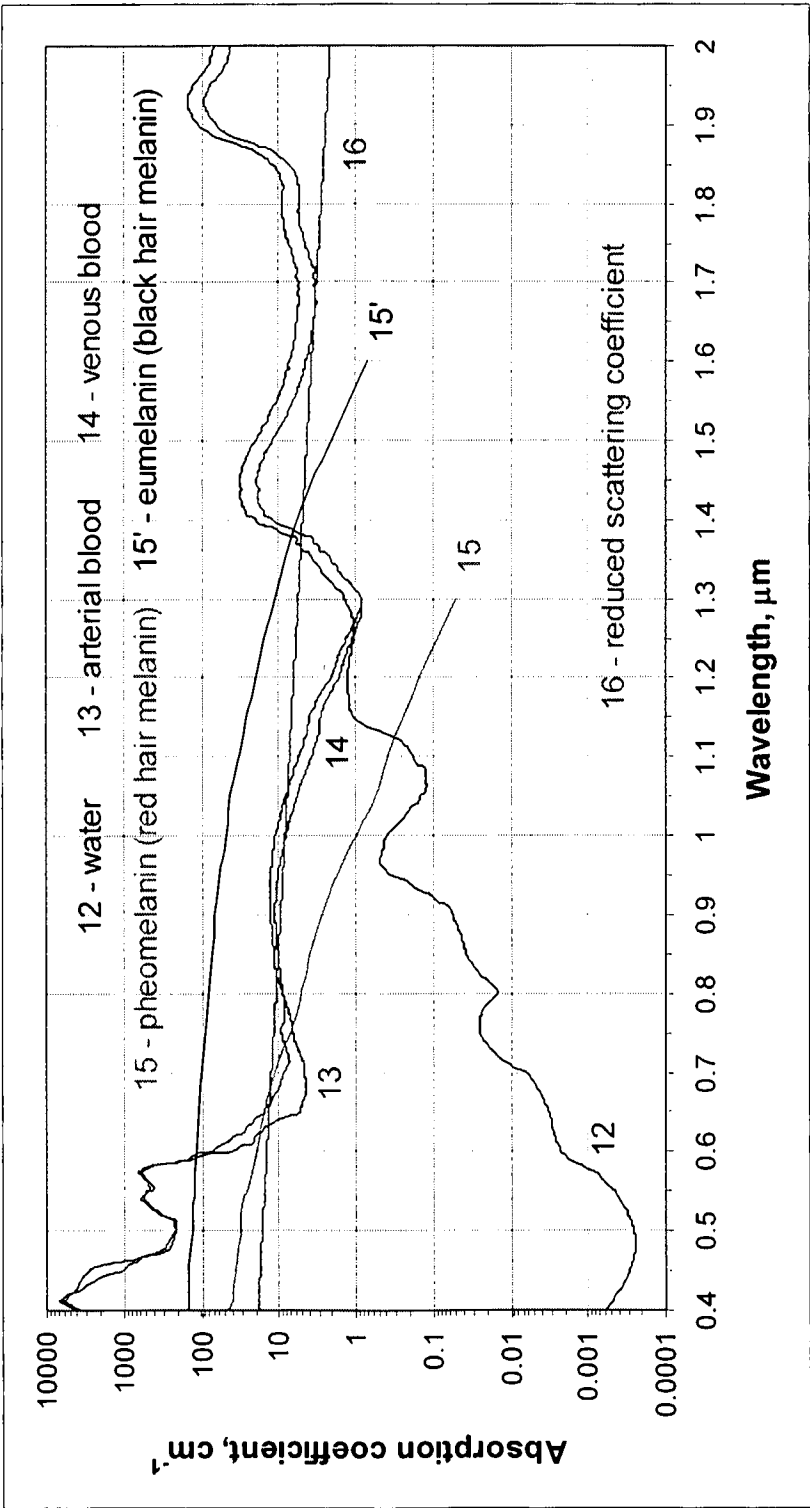


Fig. 3

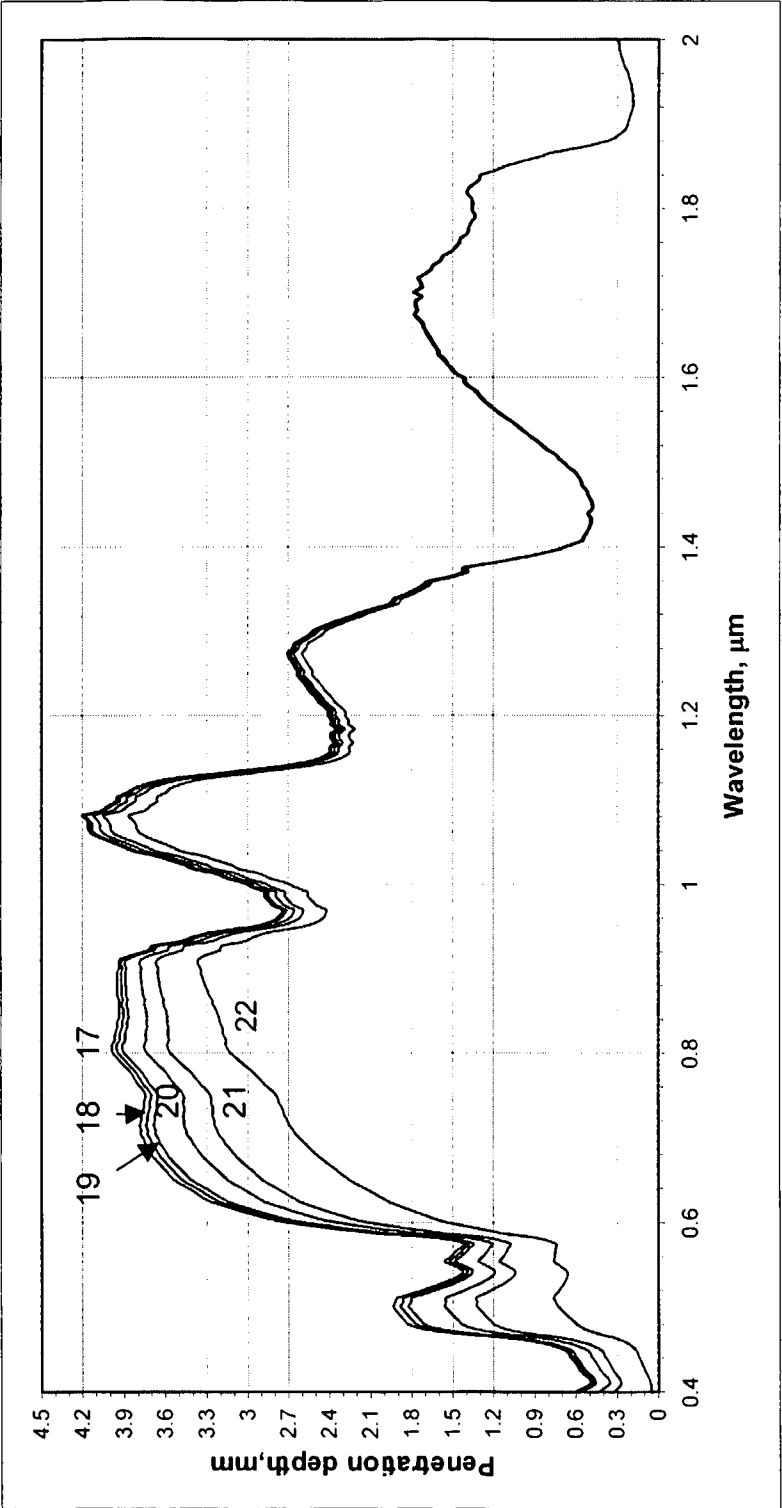


Fig. 4

- 24 – (1ms, Tc 9940K)
- 25 – (5ms, Tc 7528K)
- 26 – (20ms, Tc 5925K)
- 27 – (50ms, Tc 5058K)
- 28 – (100ms, Tc 4448K)
- 29 – (200ms, Tc 3982K)
- 30 – (500ms, Tc 3399K)

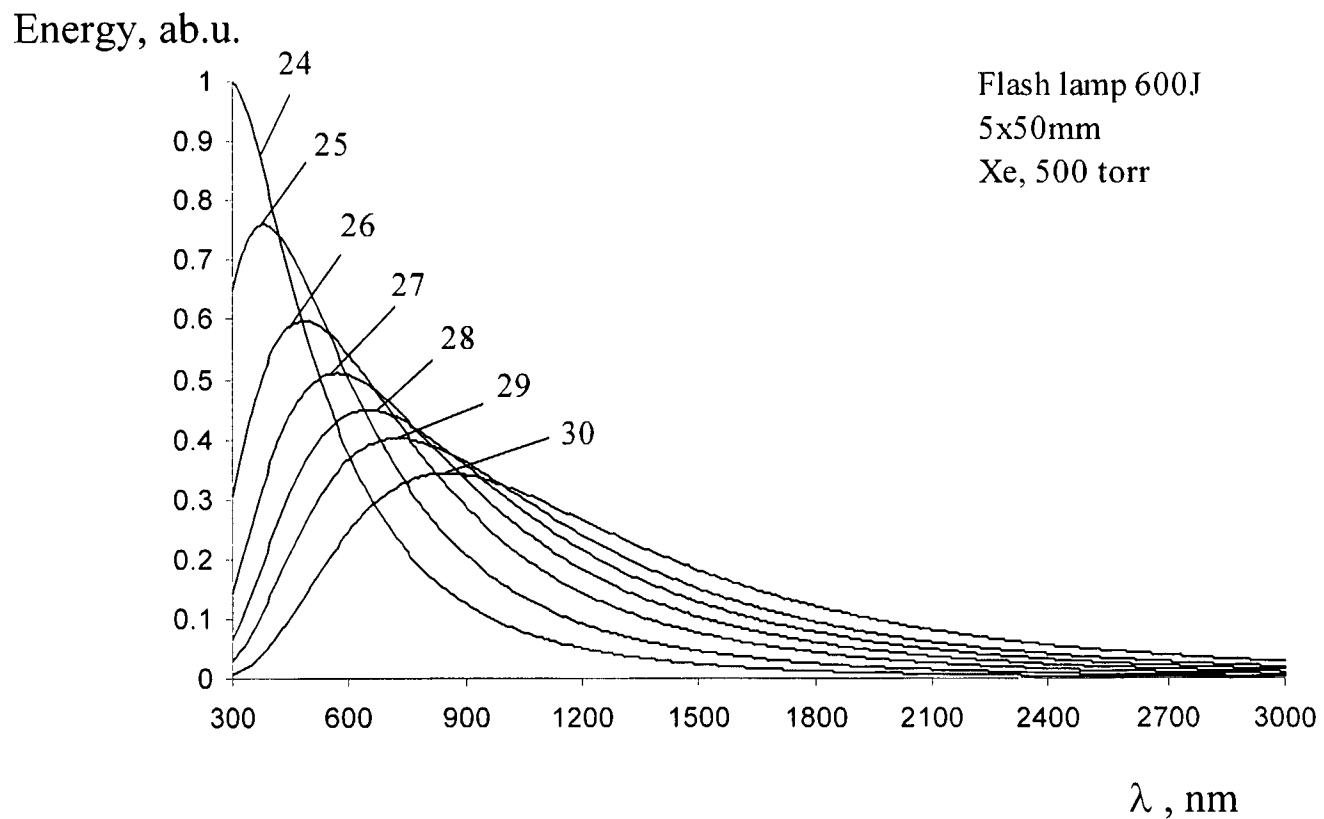


Fig. 5

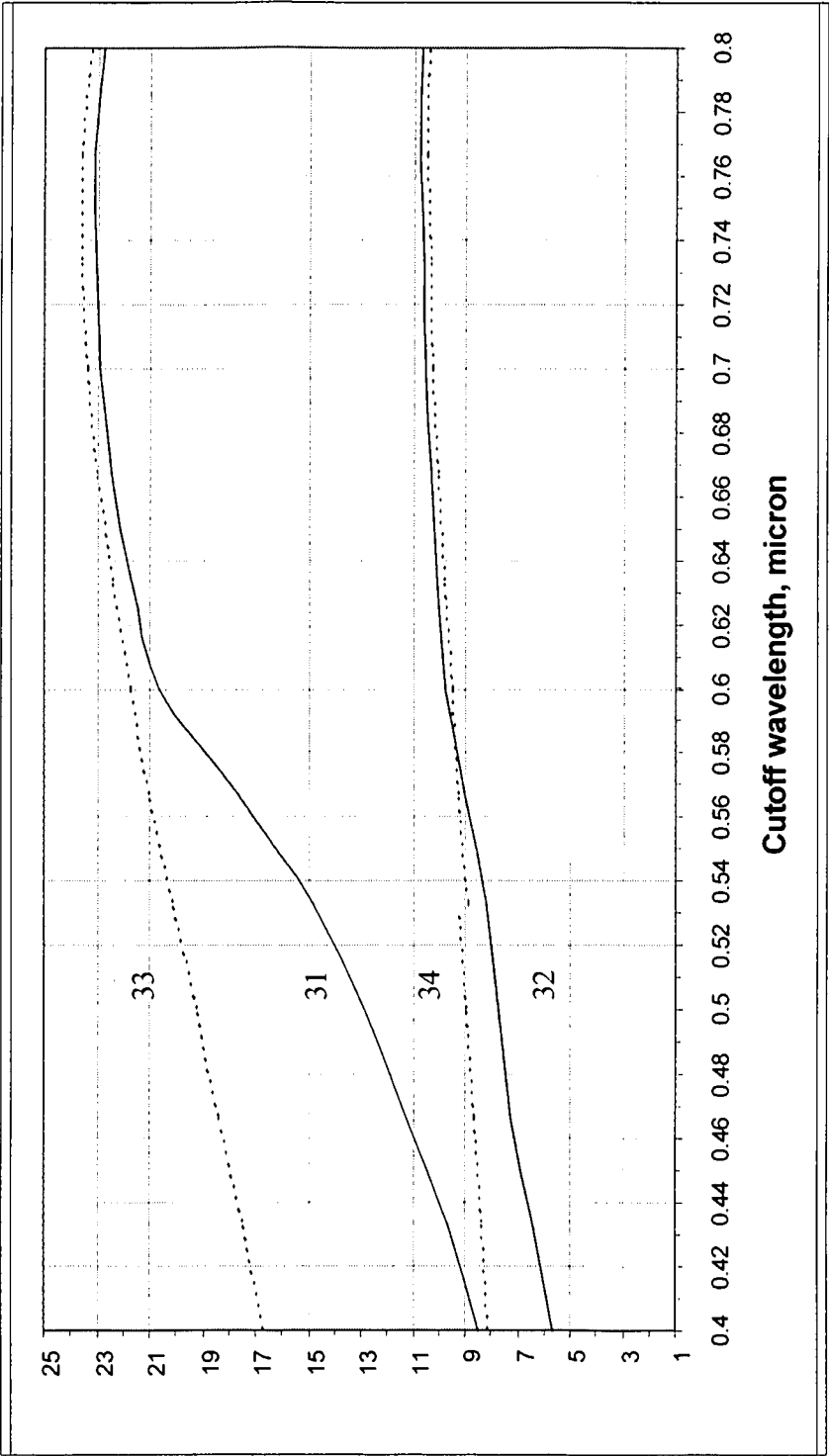


Fig. 6a

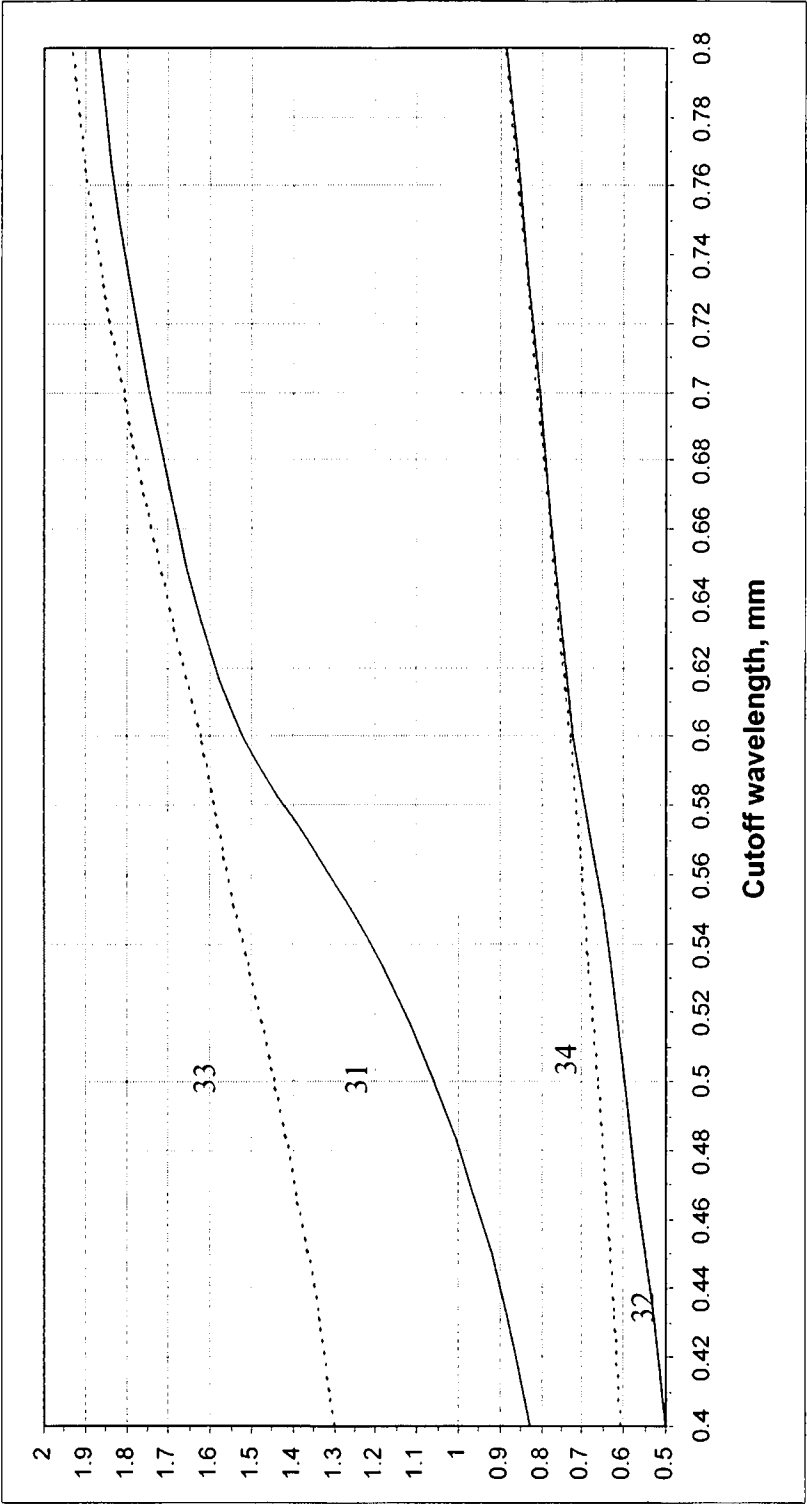


Fig. 6b

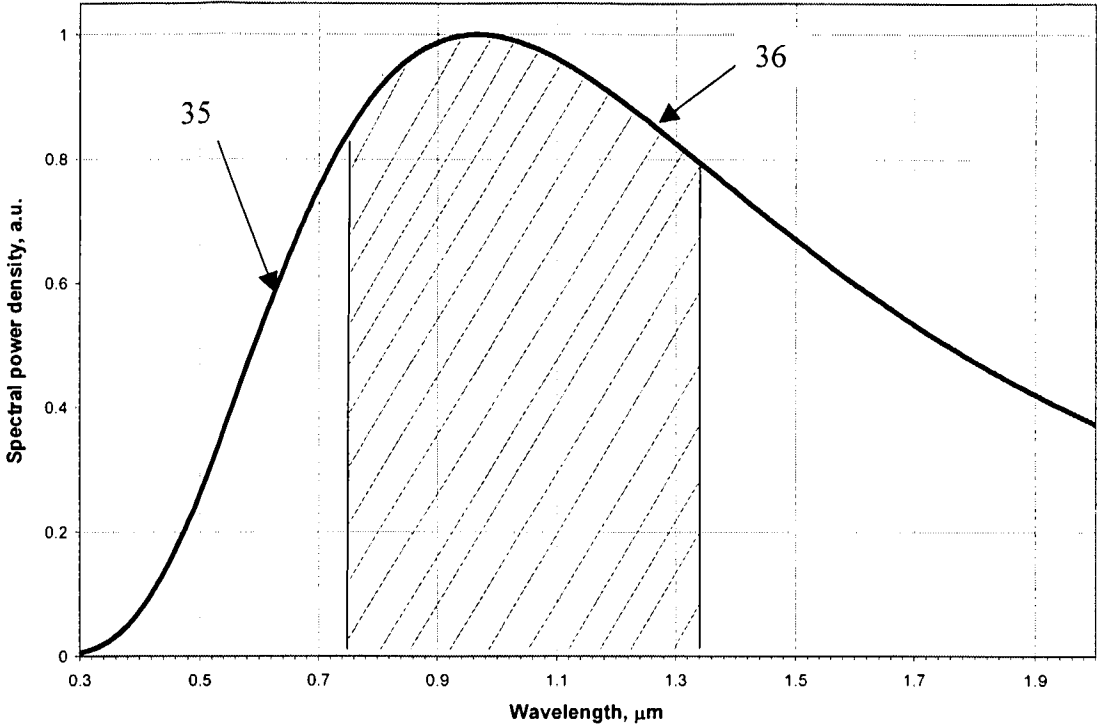


Fig. 7a

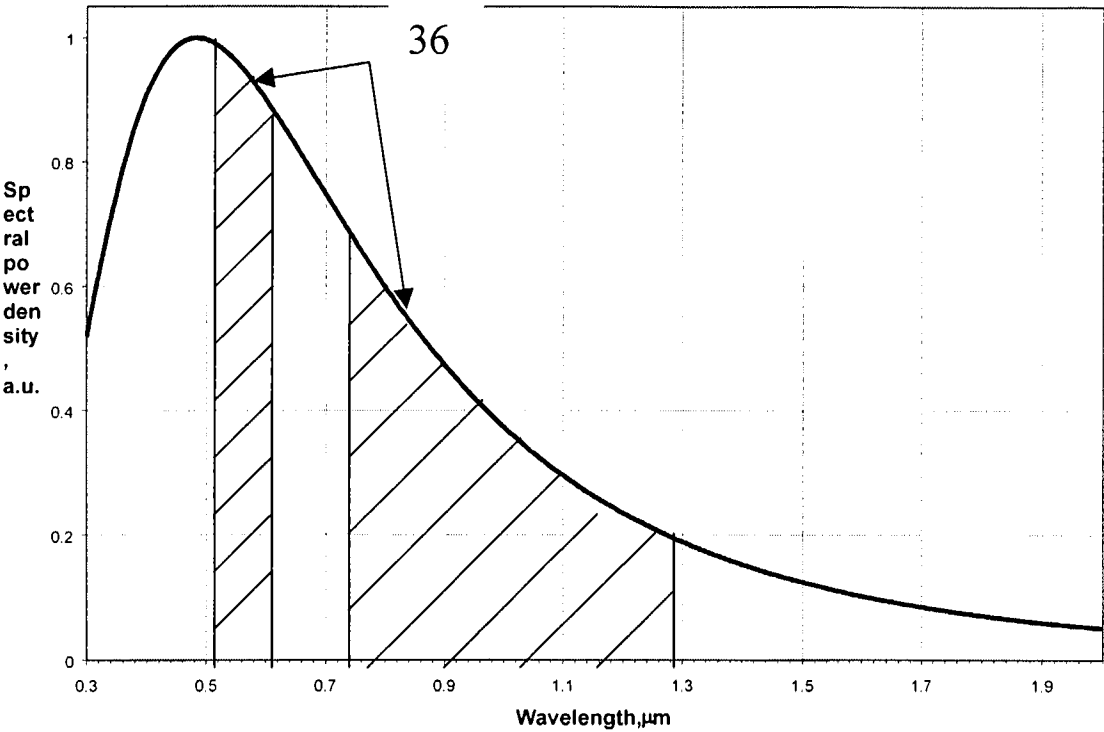


Fig. 7b

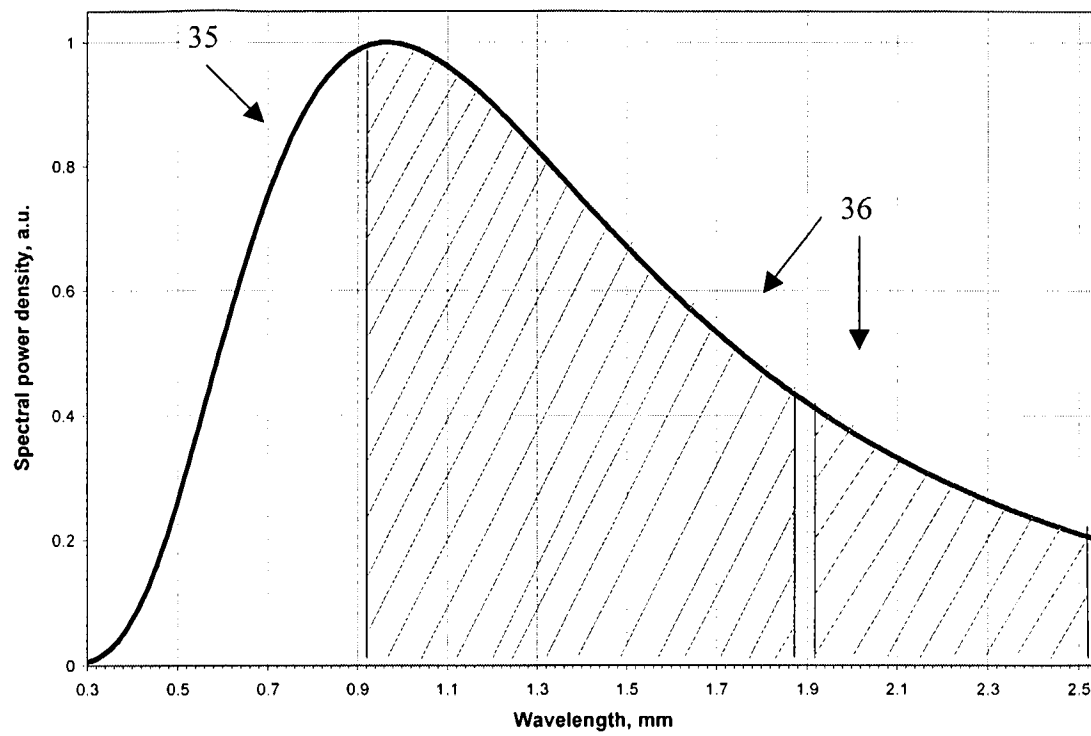


Fig. 7c

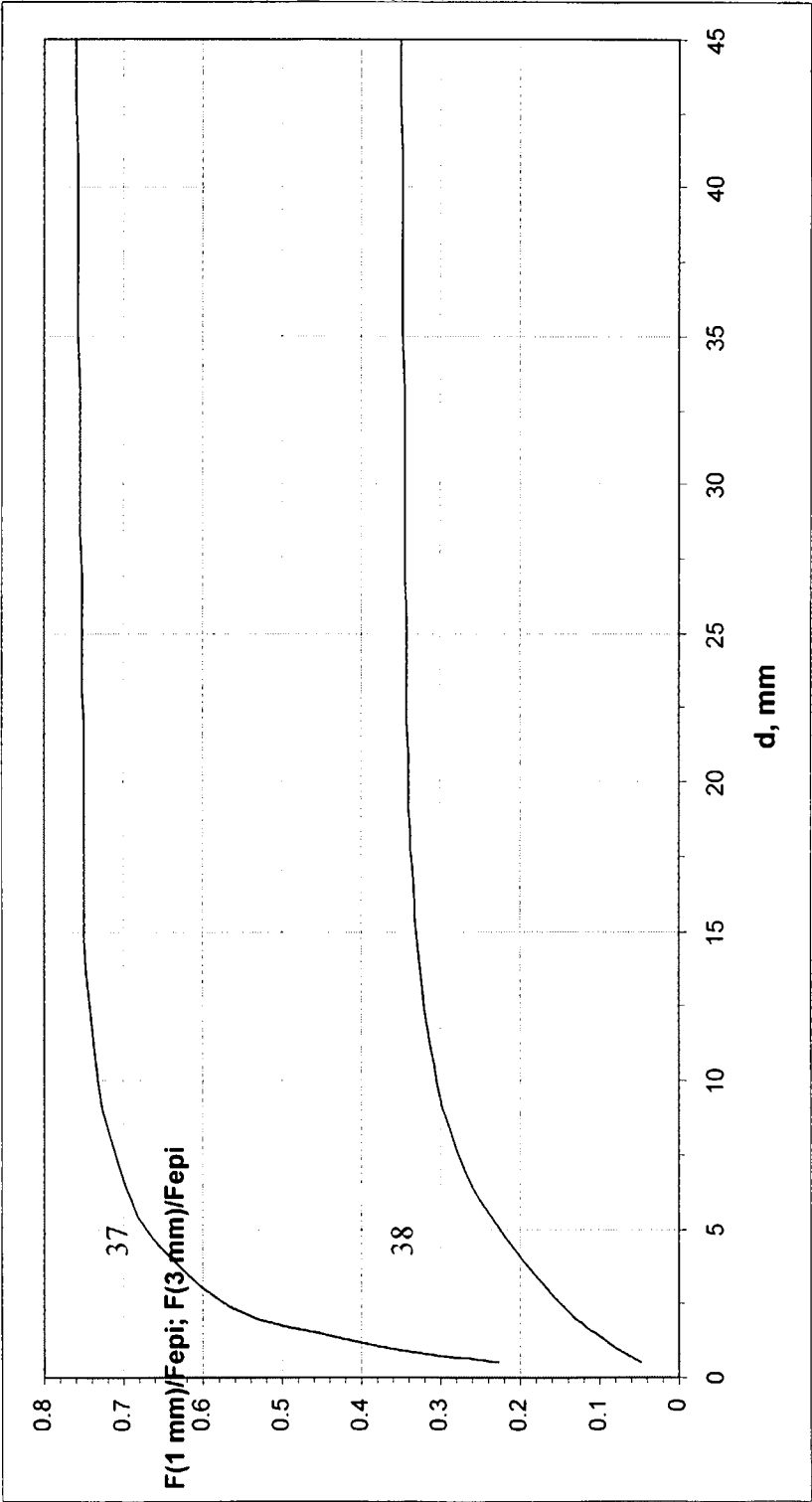


Fig. 8

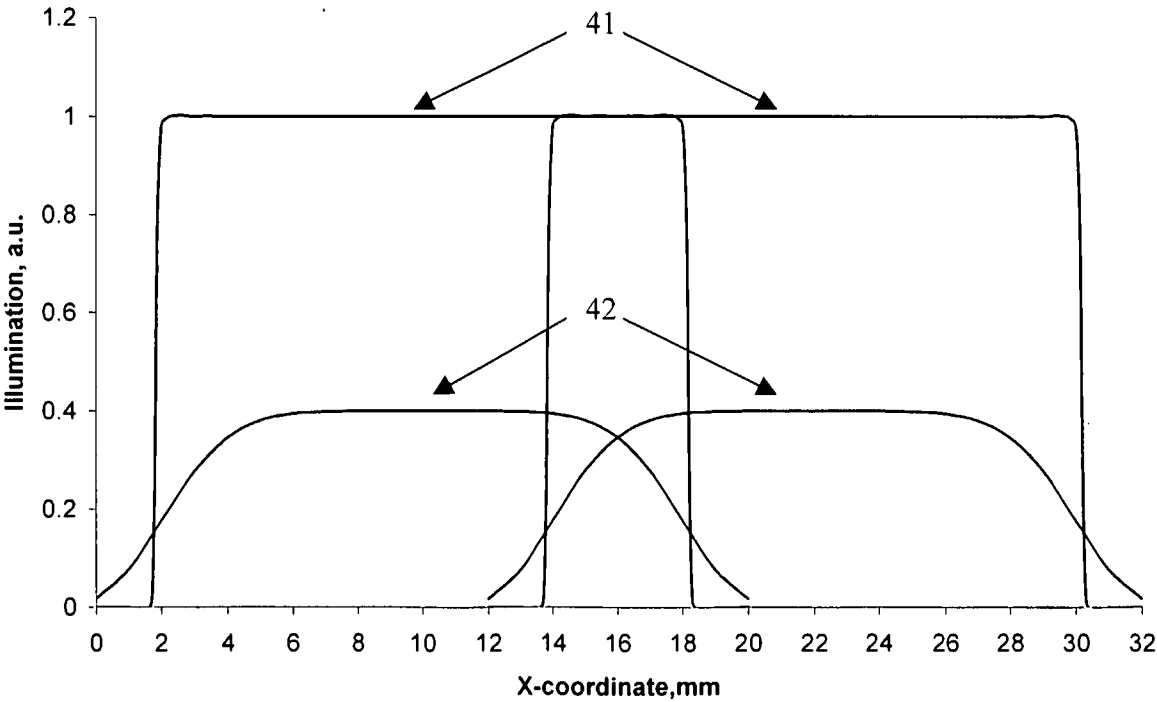
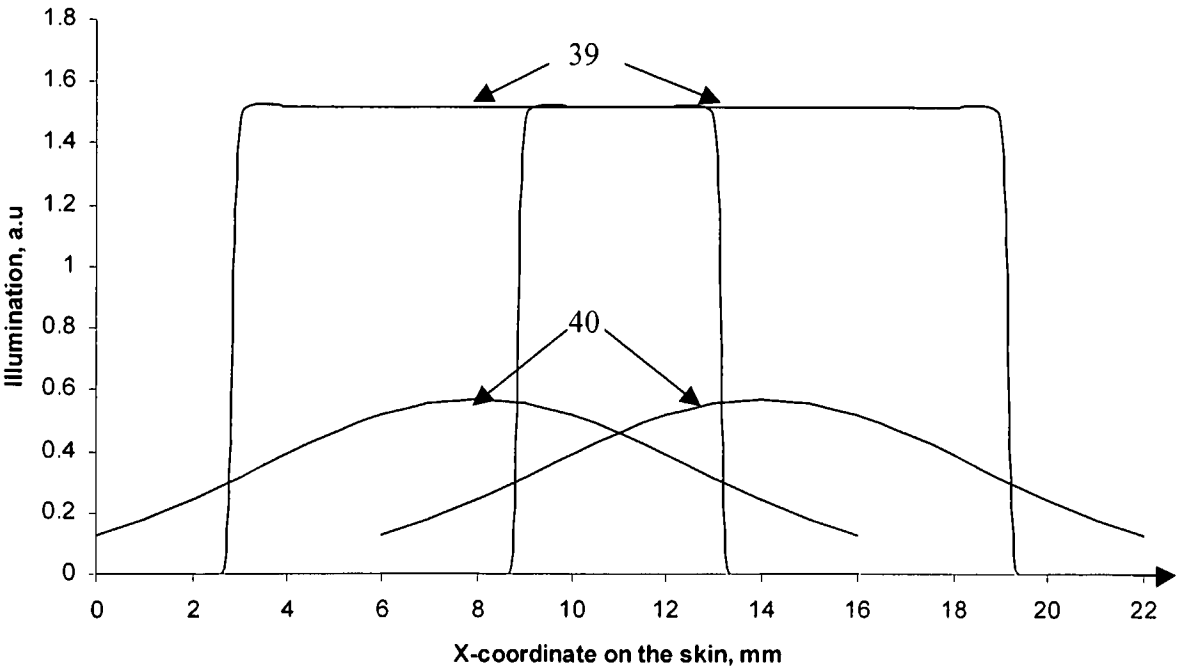


Fig. 9

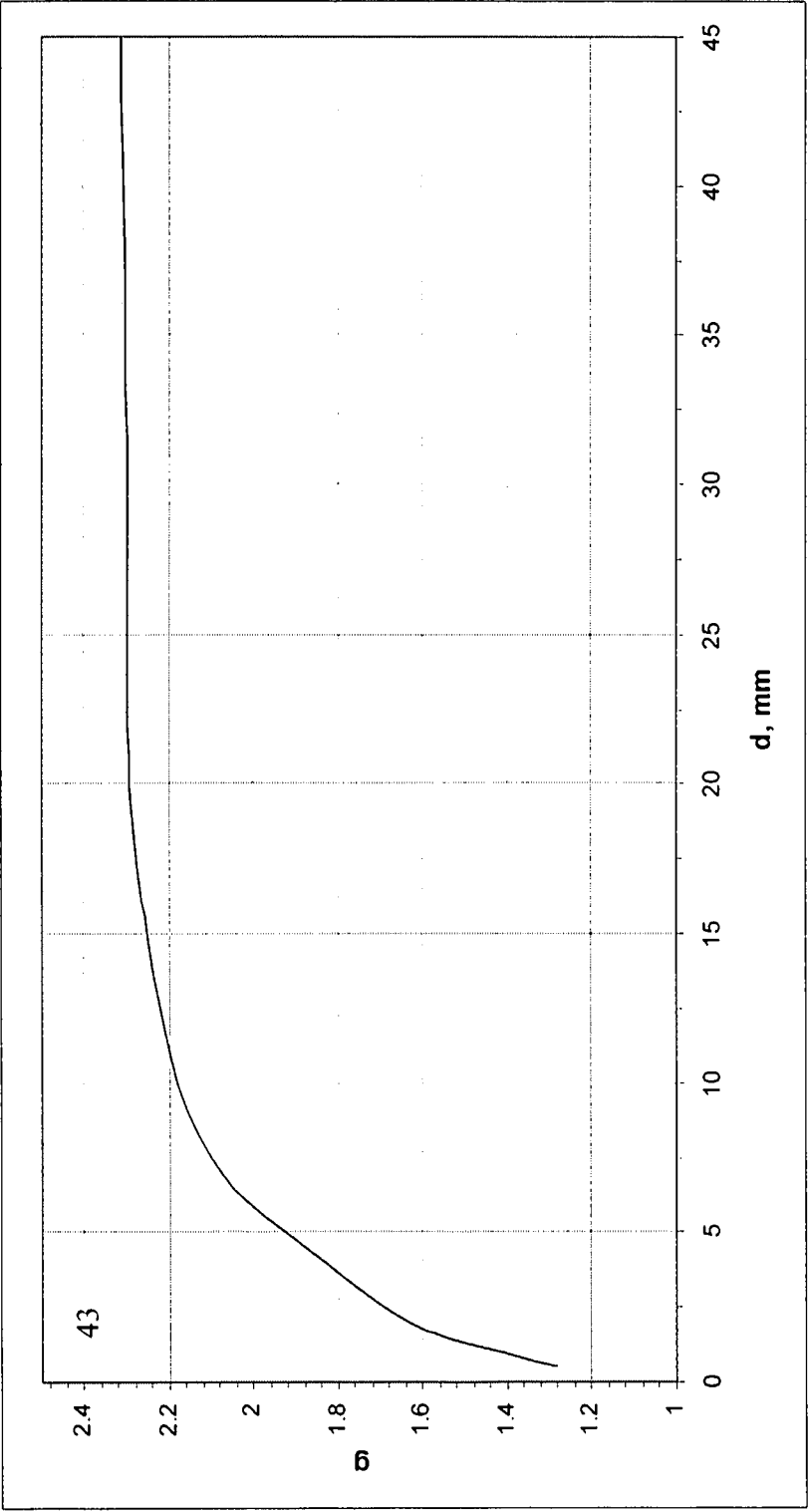


Fig. 10

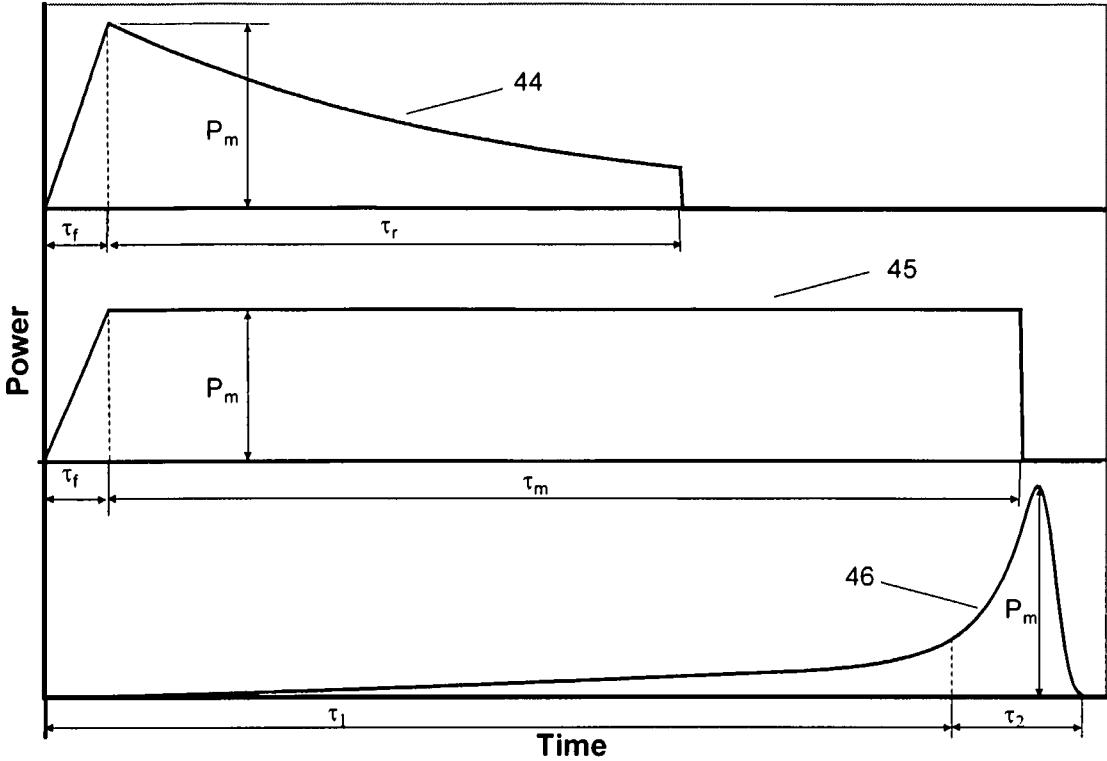


Fig. 11

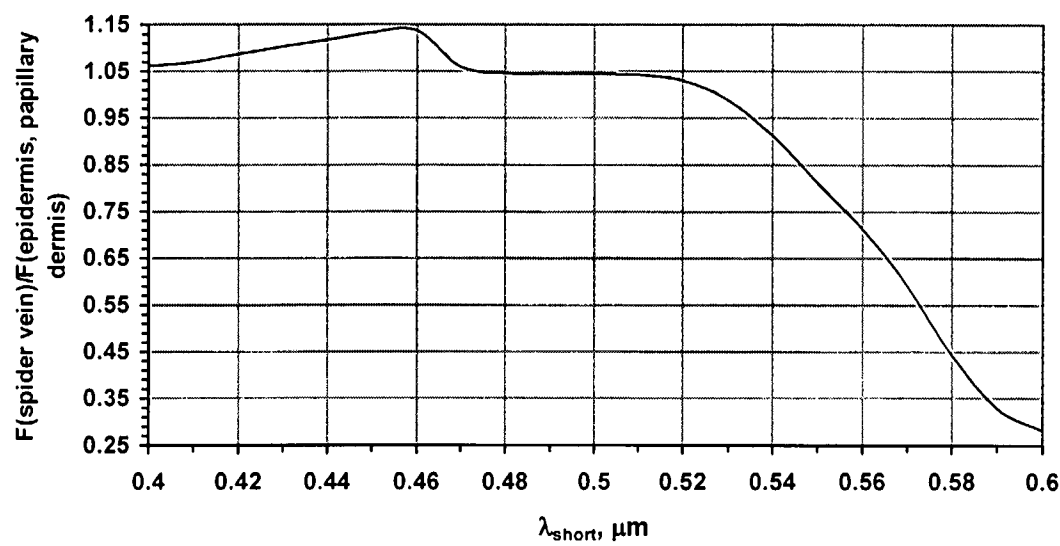


Fig. 12

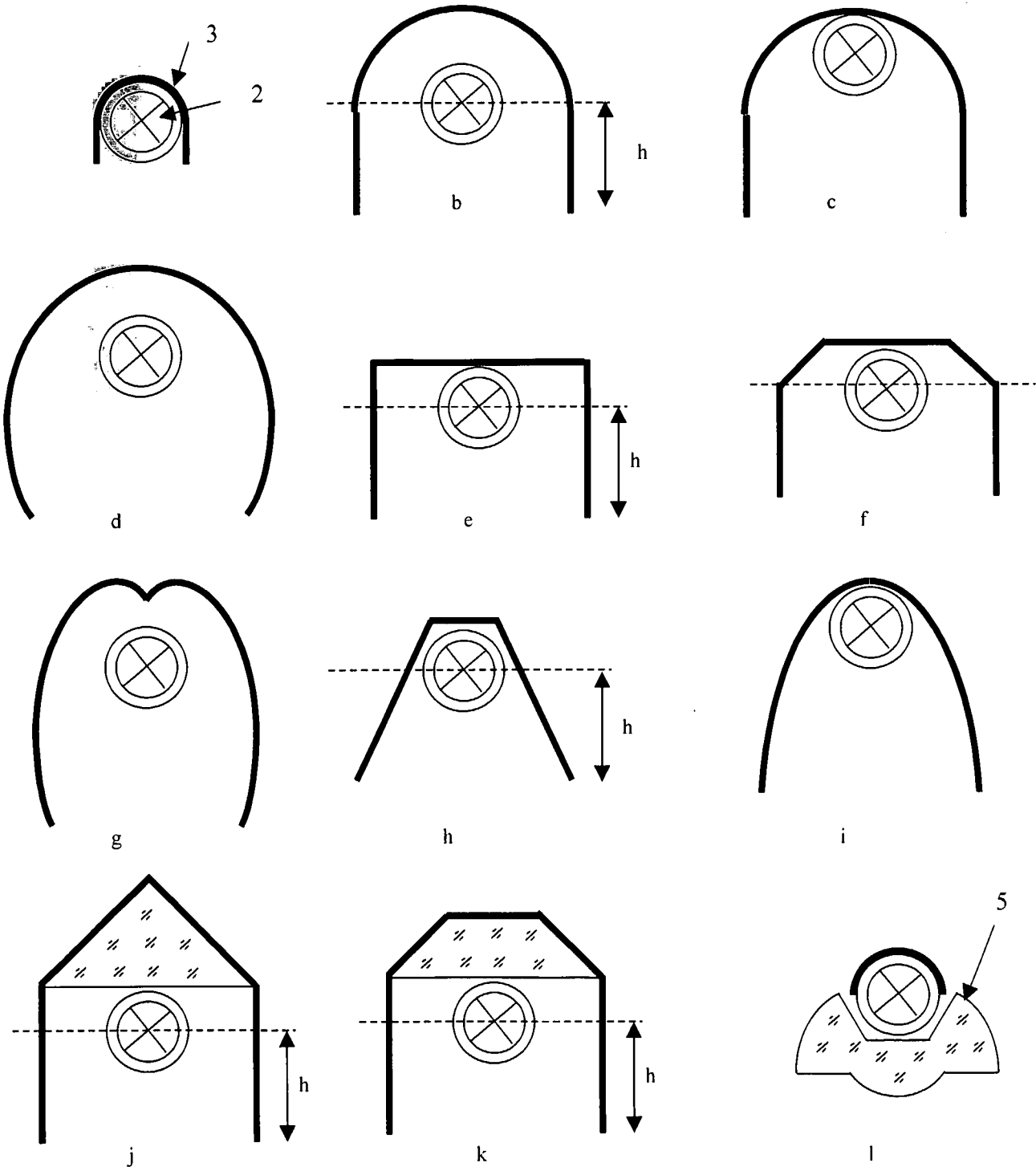


Fig. 13

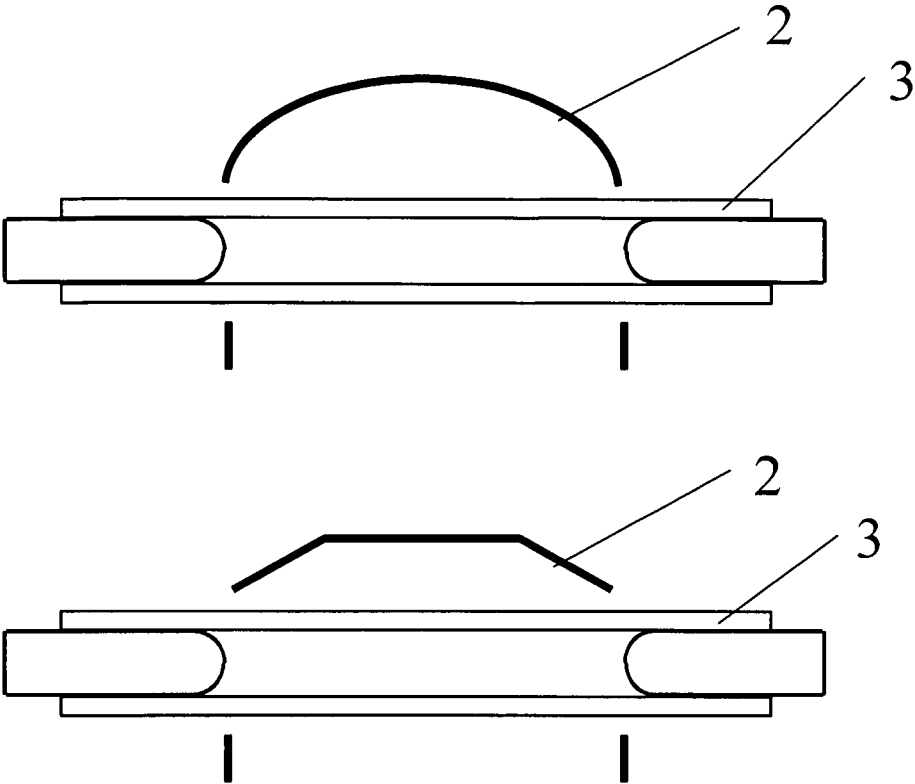


Fig. 14

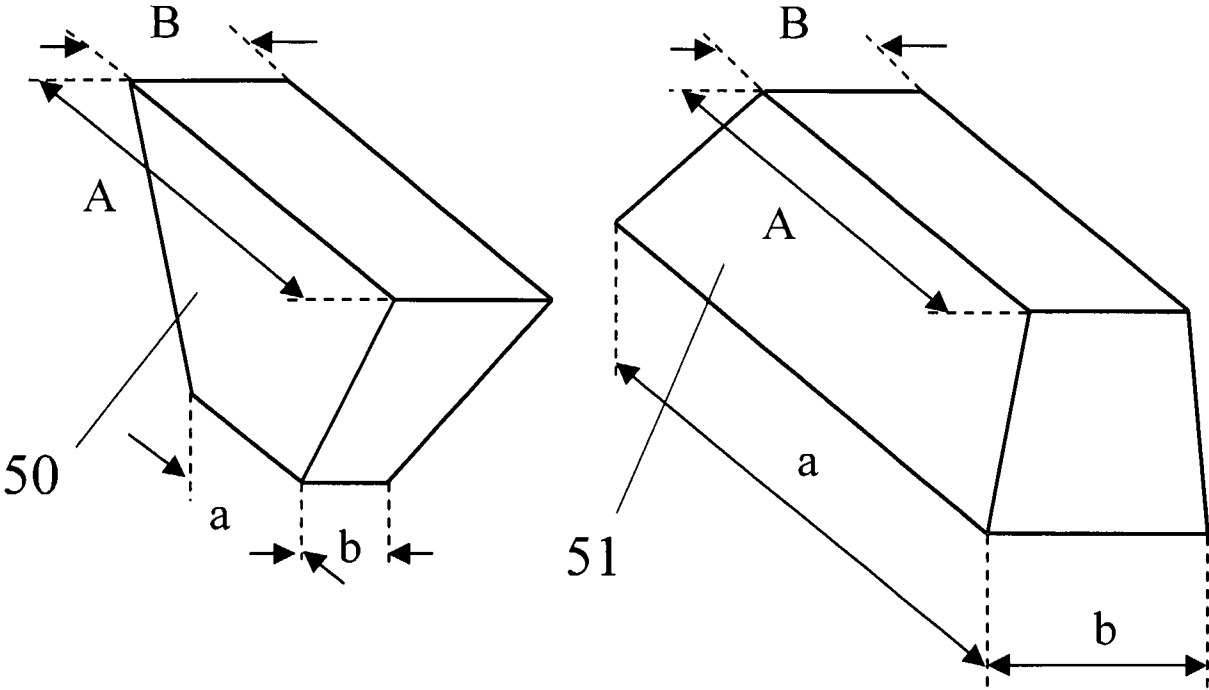


Fig. 15

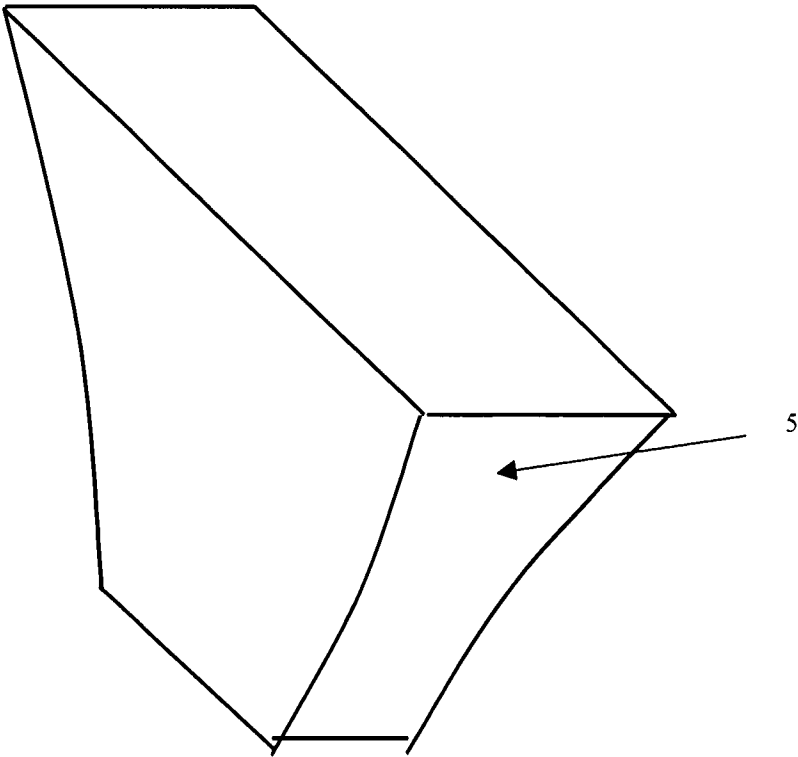


Fig. 16

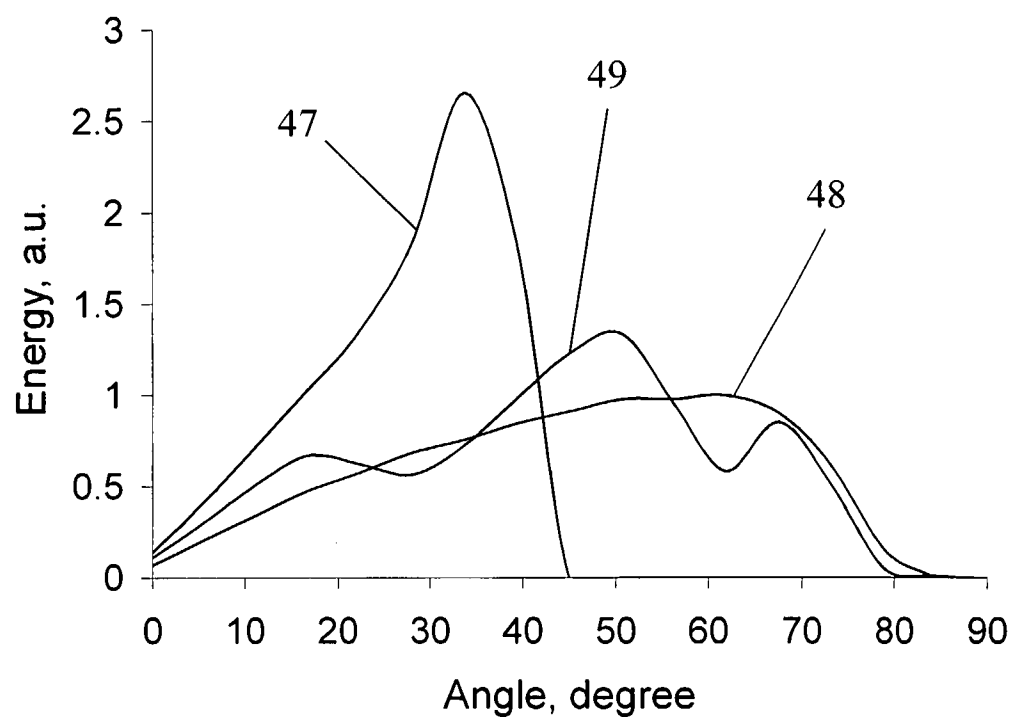


Fig. 17

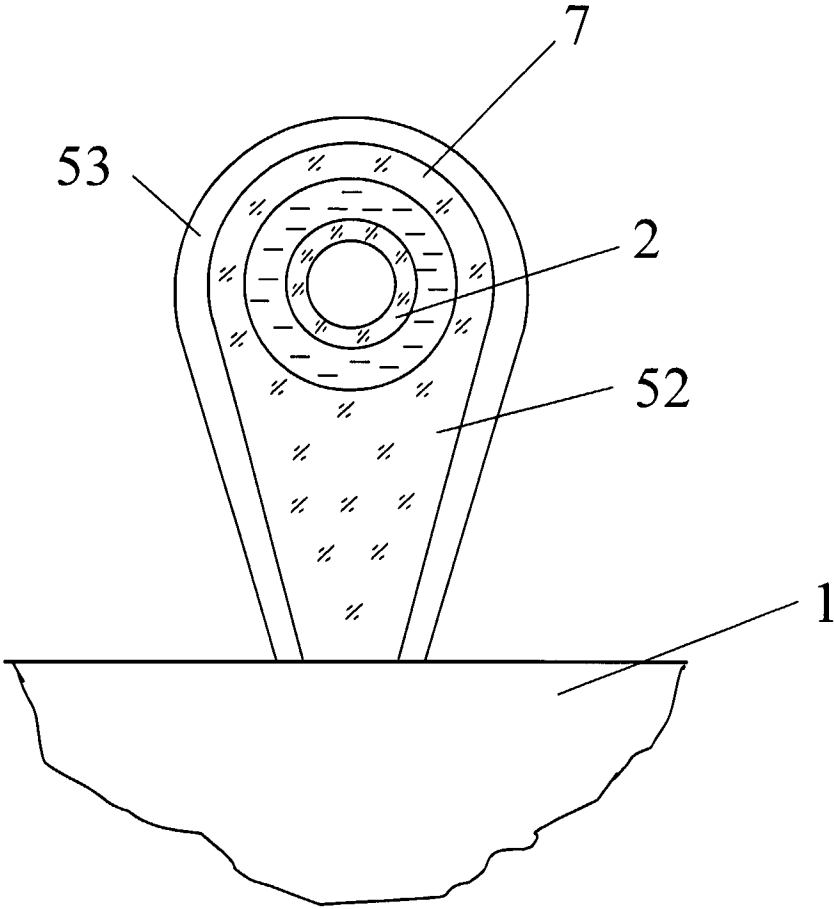


Fig. 18

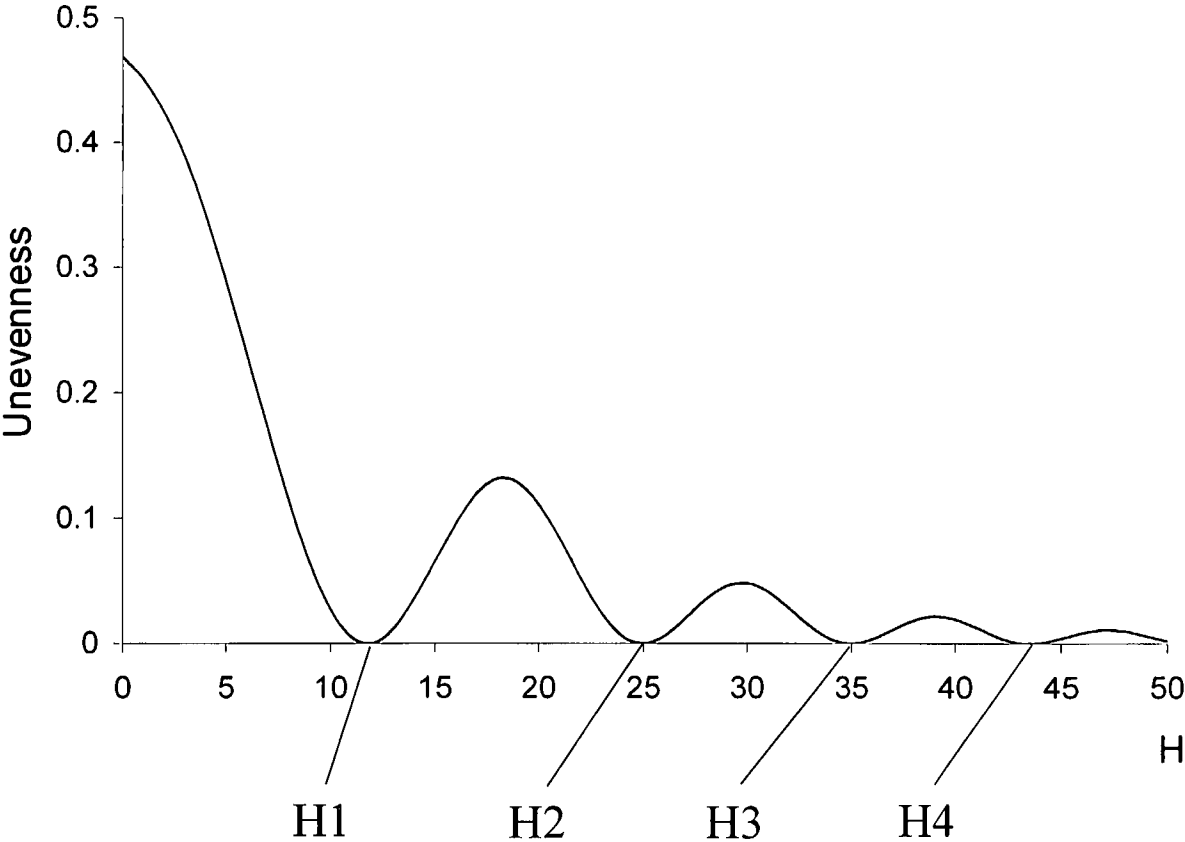


Fig. 19

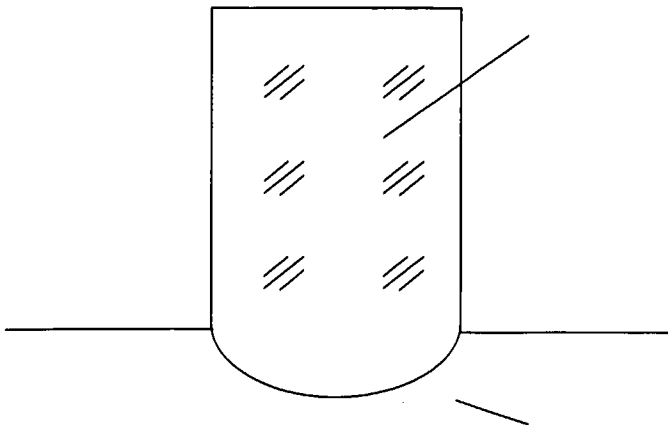


Fig. 20a

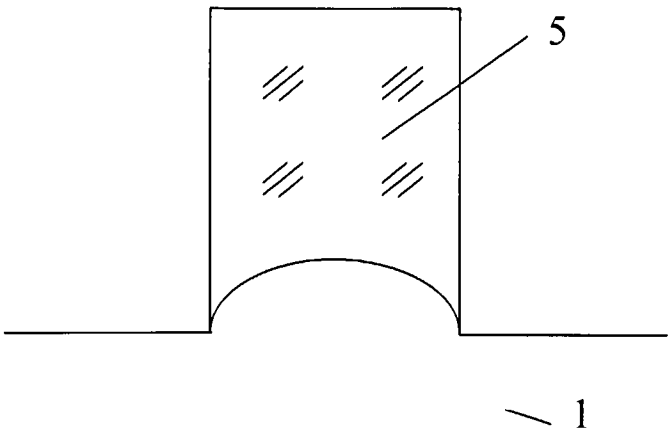


Fig. 20b

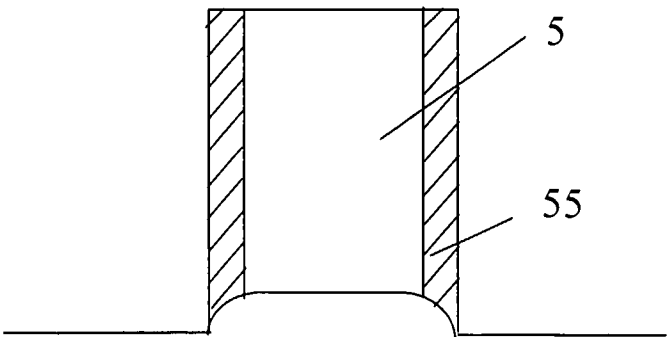


Fig. 20c

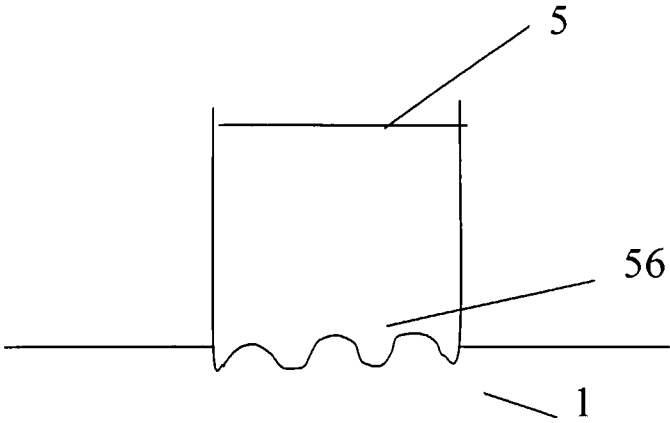


Fig. 20d

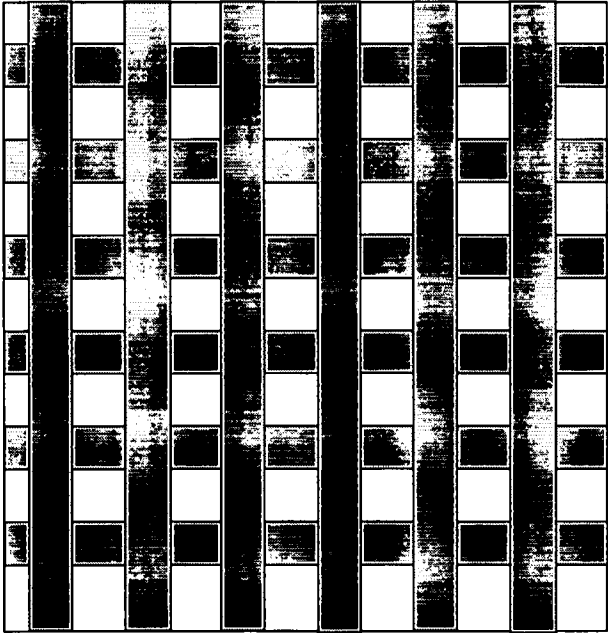
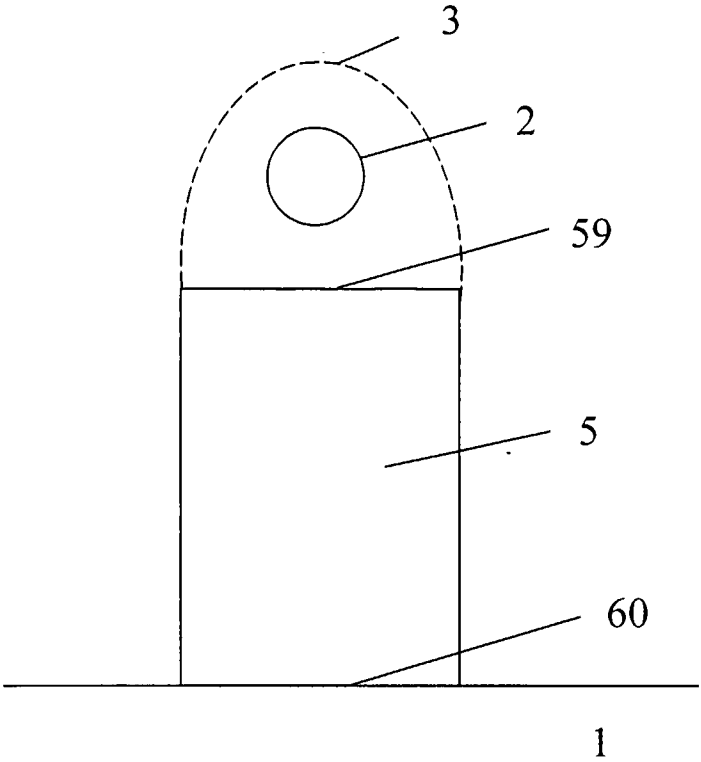
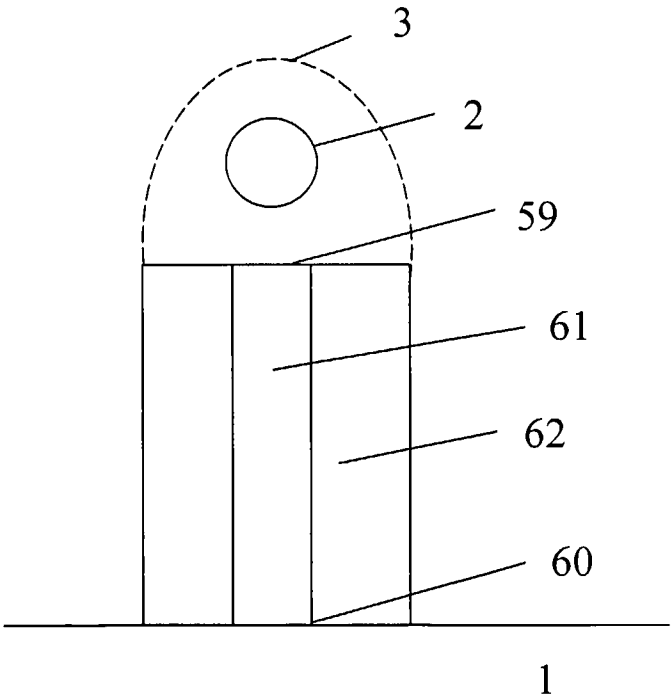


Fig. 20e



a.



b.

Fig. 21

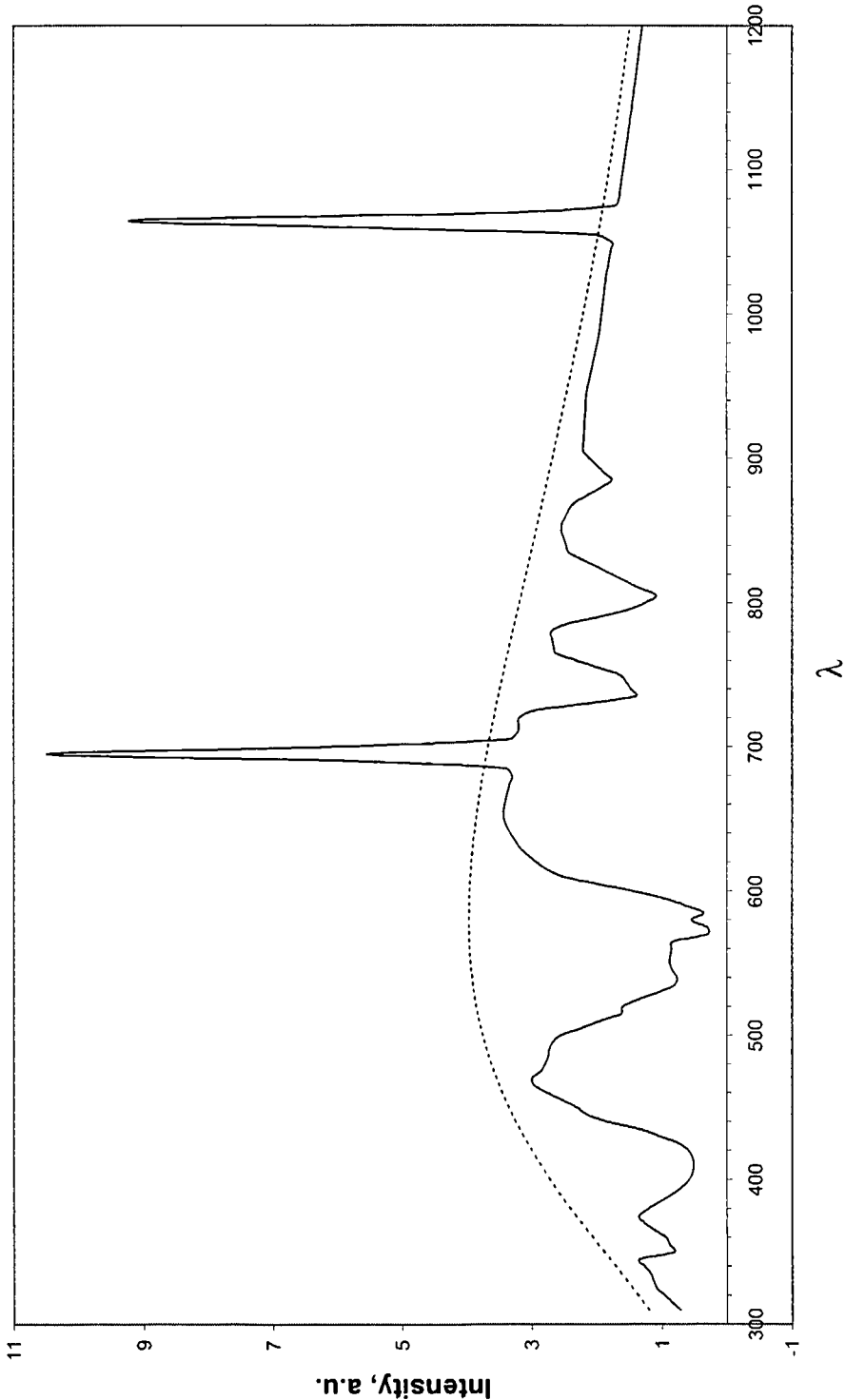


Fig. 22

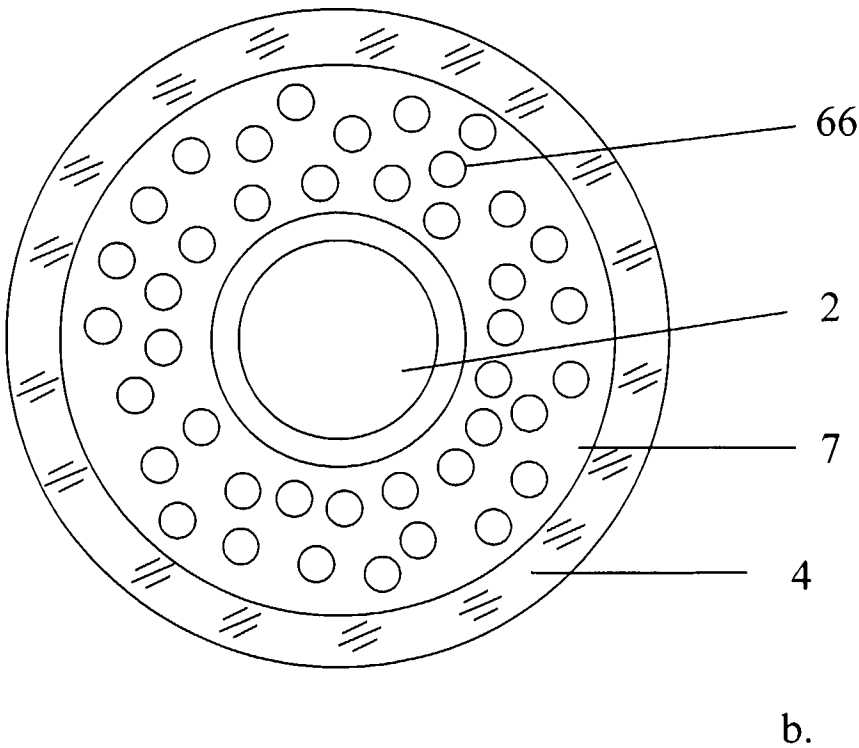
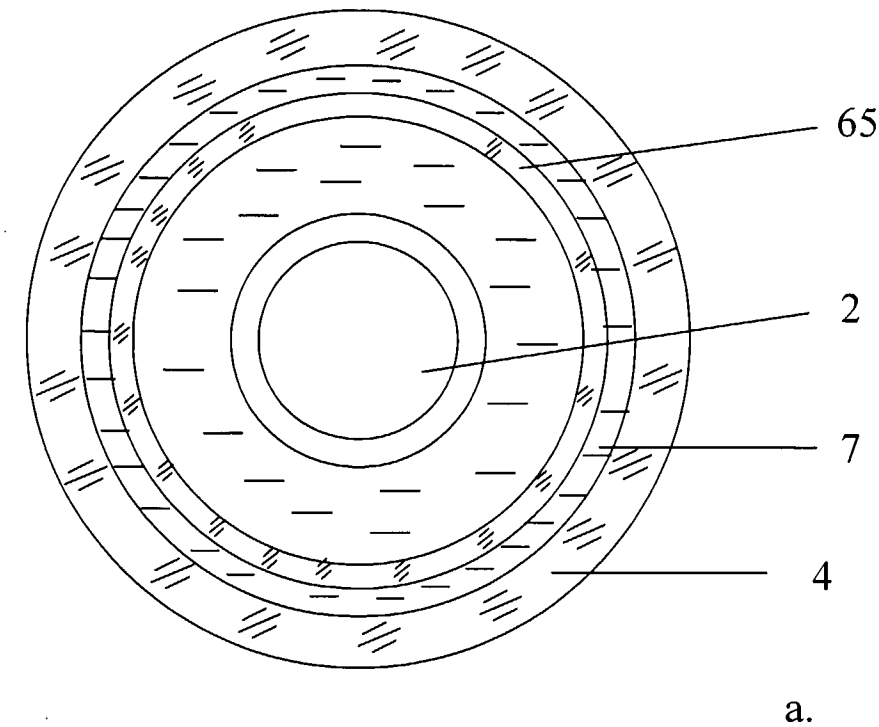


Fig. 23

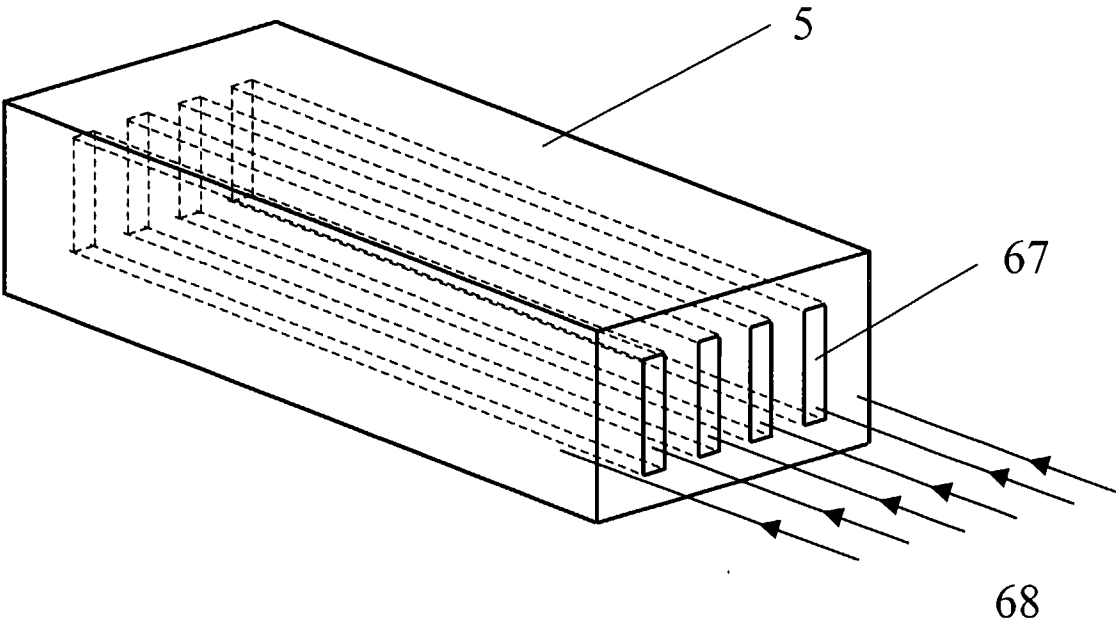


Fig. 24

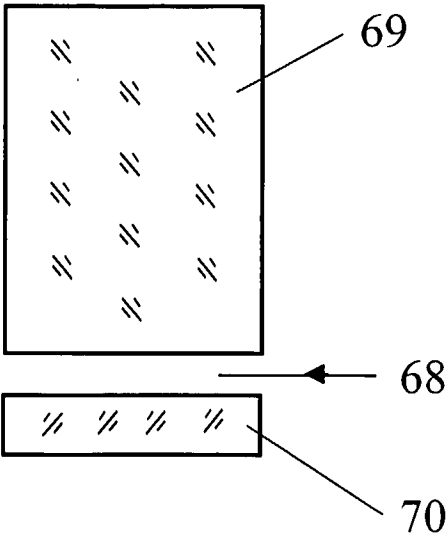


Fig. 25

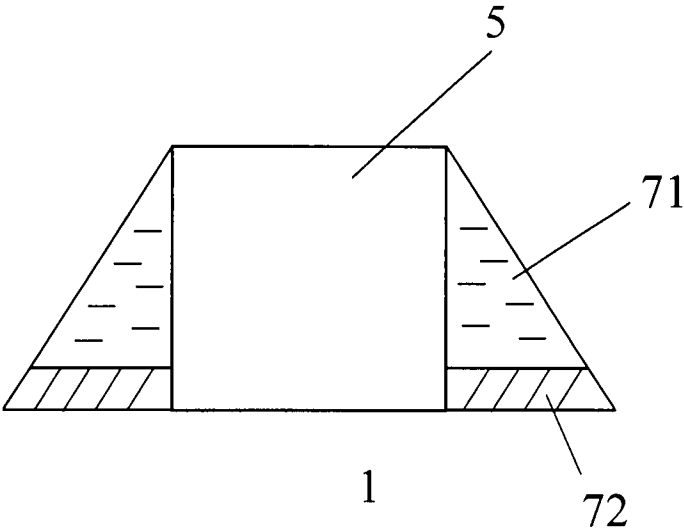


Fig. 26

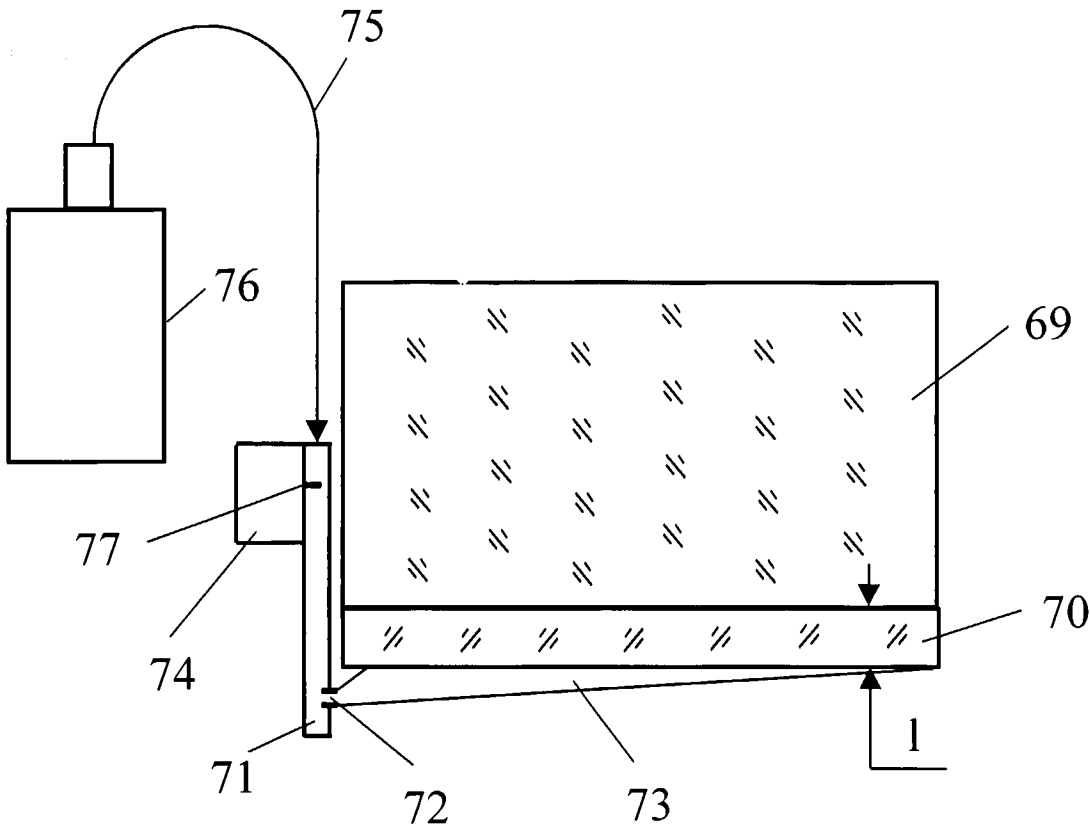


Fig. 27

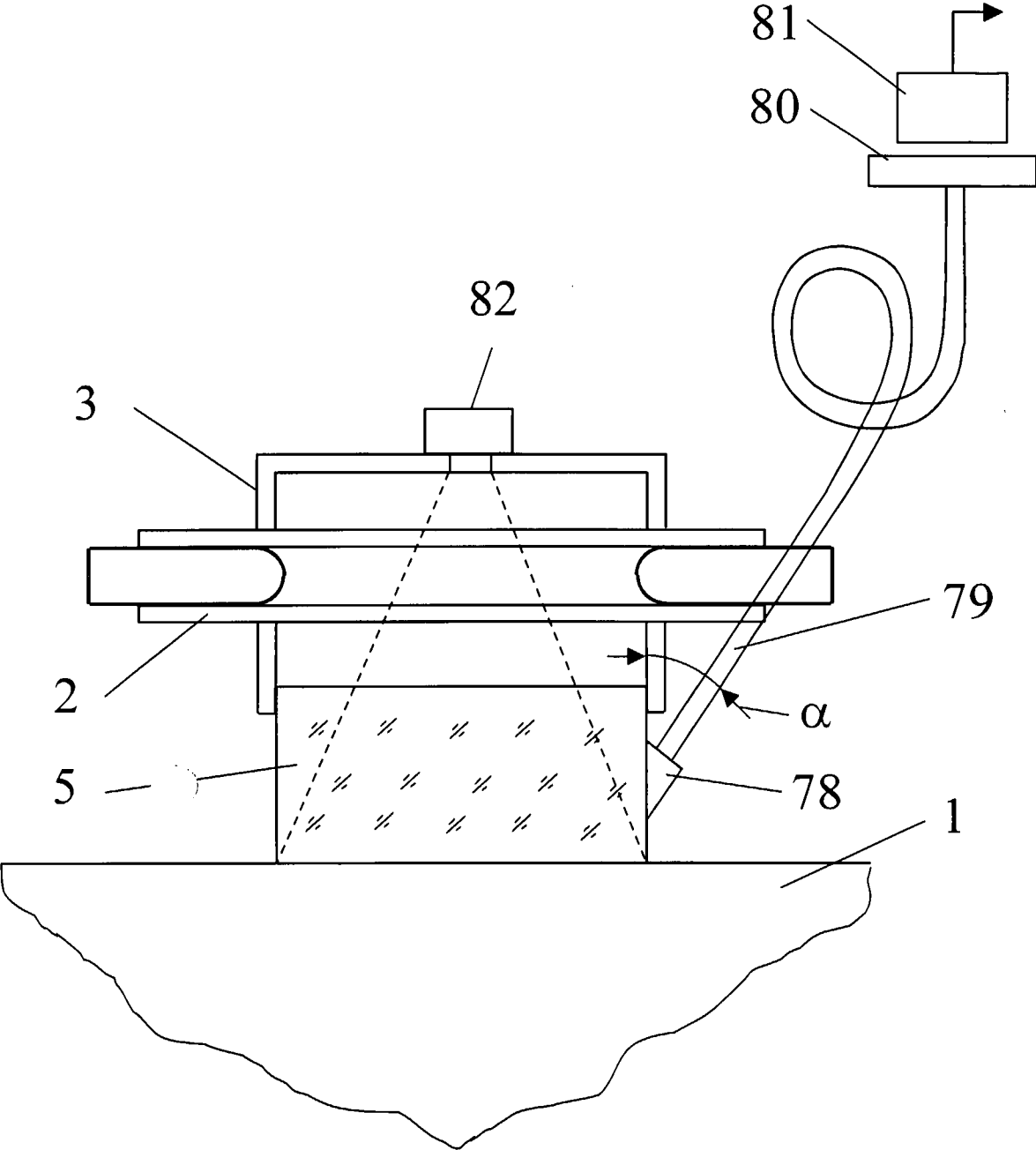


Fig. 28

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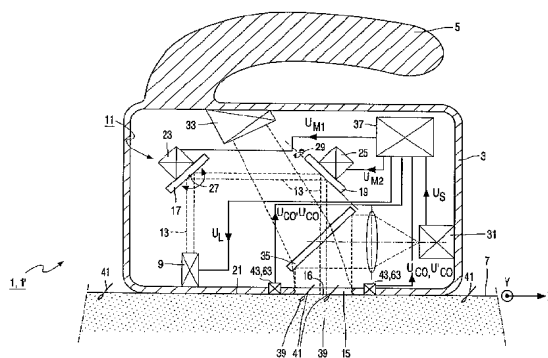
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SKIN TREATING DEVICE COMPRISING A PROTECTED RADIATION EXIT OPENING



(57) **Abstract:** The invention relates to a device (1) for the treatment of skin (7) by means of radiation. The device comprises a housing (3) accommodating a radiation source (9) and having an exit opening (15) for the radiation. The device has a control unit (37) which activates the radiation source only if the presence of the skin immediately in front of the exit opening is detected by a detector (43) that co-operates with the control unit. As a result, the radiation source cannot be activated if the exit opening is not covered. Preferably, the detector is suitable for measuring a scattering and/or absorption coefficient of the skin for light having a predetermined wavelength. Alternatively, the detector is suitable for measuring a reflection coefficient of the skin for light having a predetermined wavelength. In a preferred embodiment, in which the detector is provided in a skin contact element (21) in which the exit opening (15) is provided, the detector also detects the presence of the skin against the skin contact member. The invention can be used, for example, in a hair removing device (1, 1', 83) such as a laser epilator, a laser shaver or a flashlight epilator, but also in devices for the medical treatment of skin by means of radiation, such as photodermatology systems.

Skin treating device comprising a protected radiation exit opening

The invention relates to a device for treating skin by means of radiation, which device comprises a housing, which accommodates a radiation source and which is provided with an exit opening for the radiation, a detector for detecting the presence of skin directly in front of the exit opening, and a control unit which activates the radiation source only if the
5 detector detects the presence of skin directly in front of the exit opening.

A device of the type mentioned in the opening paragraph is known from JP-A-5-57026. The known device is a device for the medical treatment of skin by means of laser
10 light. The device is used, for example, for treating birthmarks, such as naevus pigmentosus and naevus vinosus, present on the skin, psoriasis, or aberrations of blood vessels present in the skin. In the housing of the device two laser sources are arranged which, in operation, each generate a laser beam. The laser beams are obliquely oriented with respect to the exit opening. If the housing is correctly placed on the skin, i.e. if the skin is present directly in
15 front of the exit opening and hence the exit opening is completely covered and enclosed, the obliquely oriented laser beams are reflected by the skin and said reflected laser beams are incident on two photosensors that are also arranged in the housing. If the skin is not present directly in front of the exit opening, for example if the device is obliquely positioned on the skin or at some distance from the skin, the reflected laser beams do not, or only partly,
20 impinge on the two photosensors. In this state, the control unit co-operating with the photosensors deactivates the two laser sources. In this manner, emission of the laser beams via the exit opening is impeded if the exit opening is not fully covered and enclosed, so that accidentally or deliberately harming or injuring someone by means of the laser beams is impeded substantially.

25 A drawback of the known device resides in that it is not optimally protected against accidental or deliberate emission of laser beams via the exit opening. For example, the protection is sub-optimal if the exit opening is covered with a glass plate, since the laser beams are partly reflected by the glass plate, so that the laser beams are still incident on the photosensors. The laser beams are not deactivated either if the exit opening is covered with

another material that partly reflects the laser beams, as a result of which there may be a fire risk. Due to said drawback, the device is less suitable for the consumer market.

5 It is an object of the invention to provide a device of the type mentioned in the opening paragraph, the radiation source of which can be activated only if the medium present directly in front of the exit opening actually is human skin, so that optimum protection against accidental or deliberate emission of radiation via the exit opening is achieved and the device is more suited for the consumer market.

10 To achieve this object, a device of the type mentioned in the opening paragraph is characterized in accordance with the invention in that the detector can suitably be used to measure a biophysical property by means of which the skin can be characterized, the control unit comprising a comparator for comparing a value or condition of the property, measured by means of said detector, with a skin-characteristic value or condition of the
15 property. In the device in accordance with the invention, the radiation source is activated or deactivated by the control unit on the basis of the comparison made by the comparator. The radiation source is activated by the control unit only if the value or condition of said biophysical property, measured by the detector, corresponds, within predetermined limits, to the human skin-characteristic value or condition of said property. By using a biophysical
20 property enabling the skin to be characterized in a substantially unique way, a very reliable protection of the device against accidental or deliberate emission of the radiation via the exit opening is achieved, and the radiation source can be activated only if the medium present directly in front of the exit opening actually is human skin. By virtue thereof, the device can particularly suitably be used for the consumer market.

25 A particular embodiment of a device in accordance with the invention is characterized in that the housing comprises a skin contact element in which the exit opening is formed and in which said detector is provided near the exit opening. As the detector is provided in said skin contact element, the control unit activates the radiation source only if the detector detects the presence of human skin against the skin contact element. By virtue
30 thereof, it is more effectively prevented that the radiation source is activated if the skin contact element does not contact the skin, in particular if there is still a small opening between the skin contact element and the skin. The reliability of the device is further improved thereby. Preferably, the device comprises at least two detectors which are arranged at some distance from each other near the exit opening, for example on either side of the exit

opening. In this manner, it is more effectively prevented that the radiation source can be activated if the exit opening is only partly covered.

A further embodiment of a device in accordance with the invention is characterized in that a series of detectors is provided in the skin contact element around the exit opening to measure the biophysical property. In this embodiment, the control unit
5 activates the radiation source only if all detectors present in the skin contact element measure a skin-characteristic value or condition of the biophysical property and hence detect the presence of human skin against the skin contact element. The detectors are arranged at small regular distances from each other, so that it is precluded, in a substantially optimum manner,
10 that the radiation source can be activated if the exit opening is only partly covered, resulting in a substantially optimum reliability of the device.

Yet another embodiment of a device in accordance with the invention is characterized in that the detector can suitably be used to measure a scattering coefficient and/or an absorption coefficient of the skin for light of a predetermined wavelength. Due to
15 the presence of blood, water, cells, keratin and melanin in human skin, light is absorbed and scattered in the human skin in a very characteristic way as a function of the wavelength of the light. By measuring the scattering coefficient and/or the absorption coefficient for light having a predetermined wavelength by means of said detector, it is very reliably determined whether the medium that covers the exit opening is human skin.

A particular embodiment of a device in accordance with the invention is characterized in that the detector is provided with a light sensor and a light source for light of said predetermined wavelength, which light source is arranged next to the light sensor and optically separated from said light sensor, the light source and the light sensor being in contact with the skin only if the skin contact element is in contact with the skin, and the
20 detector determining the scattering coefficient and/or absorption coefficient by comparing an amount of light measured by the light sensor with an amount of light generated by the light source. As the light source is optically separated from the light sensor, the light originating from the light source cannot directly reach the light sensor. The light from the light source is capable of reaching the light sensor through scattering in the skin. In order to achieve that a
25 substantial portion of the light from the light source reaches the light sensor through scattering in the skin, it is necessary that both the light source and the light sensor, and hence also the skin contact element, are in contact with the skin. Insufficient or no contact between the skin and the light source and/or the light sensor leads to a substantial reduction of the amount of light reaching the light sensor. Thus, by means of the detector, the value of the
30

scattering coefficient and/or absorption coefficient is reliably determined and, in addition, it is reliably detected whether the skin actually contacts the skin contact element.

A further embodiment of a device in accordance with the invention is characterized in that the detector is provided with a further light source for light of a further, 5 predetermined wavelength, which light source is also arranged next to the light sensor, optically separated from said light sensor and in contact with the skin only if the skin contact element is in contact with the skin; the detector determining the scattering coefficient and/or absorption coefficient for both wavelengths by comparing the amounts of light measured by the light sensor with the amounts of light generated by the two light sources. In this further 10 embodiment, the detector determines the scattering coefficient and/or the absorption coefficient for two different wavelengths of the light. As a still better characterization of the human skin is achieved by the values of the scattering coefficient and/or absorption coefficient for two different wavelengths of the light, the reliability of the device is still further improved. In this embodiment use is made of only one light sensor, the light sources, 15 for example, alternately generating a light pulse, so that the structure of the detector is comparatively simple.

A still further embodiment of a device in accordance with the invention is characterized in that the light source and the further light source are arranged on one side of the light sensor. By virtue thereof, the light from the two light sources reaches the light 20 sensor by scattering of the light in the same part of the skin, as a result of which the accuracy of the detector is improved.

A particular embodiment of a device in accordance with the invention is characterized in that the light source is a LED, and the light sensor is a photodiode. Said LED and photodiode are comparatively inexpensive and have small dimensions, so that the price 25 and the dimensions of the detector are limited.

A further embodiment of a device in accordance with the invention is characterized in that the detector can suitably be used to measure a reflection coefficient of the skin for light of a predetermined wavelength. Due to the presence of blood, water, cells, keratin and melanin in human skin, light is reflected very characteristically by the human 30 skin as a function of the wavelength of the light. By measuring the reflection coefficient for light of a predetermined wavelength by means of the detector, it is reliably established whether the medium, that is present directly in front of the exit opening, is human skin.

A still further embodiment of a device in accordance with the invention is characterized in that the detector is provided with a light sensor and a light source for light of

said predetermined wavelength, which light source is arranged next to the light sensor and optically separated from said light sensor, the light source and the light sensor being situated at a predetermined distance from the skin only if the skin contact element is in contact with the skin, and the detector determining the reflection coefficient by comparing an amount of light measured by the light sensor with an amount of light generated by the light source. As the light source is optically separated from the light sensor, the light from the light source cannot reach the light sensor directly. The light from the light source can reach the light sensor by reflection via the surface of the skin. The amount of light reaching the light sensor depends on the reflection coefficient and on the distance from the light source and the light sensor to the skin. In order to make sure that a predetermined amount of light from the light source reaches the light sensor by reflection, it is necessary, on the one hand, that the light is actually reflected by skin, i.e. the exit opening must actually be covered by skin, and on the other hand, said predetermined distance between the skin and the light source, and between the skin and the light sensor must actually exist, i.e. the skin contact element must be in contact with the skin. In this manner, using the detector, it is reliably detected, on the one hand, whether the medium present directly in front of the exit opening is human skin and, on the other hand, whether the skin actually is in contact with the skin contact element and the exit opening is fully covered and enclosed by the skin.

A particular embodiment of a device in accordance with the invention is characterized in that the device is a hair removing device, wherein the radiation source comprises a laser source, and the device is further provided with an adjustable laser beam manipulator for positioning a laser beam supplied, in operation, by the laser source in a target position on the skin to be treated. In such an embodiment of the device in accordance with the invention, the invention becomes effectual in a particular way because the laser beam generated by the laser source has a comparatively high light intensity and hence, in the event of accidental or deliberate emission via the exit opening, is capable of causing substantial damage or inflict serious injuries, particularly, to the eyes.

A further embodiment of a device in accordance with the invention is characterized in that the device is a hair removing device, wherein the radiation source comprises a flash light for generating light pulses, and the device is further provided with a directing element for directing the light pulses to the exit opening. In such an embodiment of the device in accordance with the invention, the invention also becomes effectual in a particular way because the light pulses generated by the flash light have a comparatively high light intensity and hence, in the event of accidental or deliberate emission via the exit

opening, are capable of causing substantial damage or inflict serious injuries, in particular, to the eyes.

5 In the following, embodiments of the device in accordance with the invention are explained in detail with reference to the figures, in which:

Fig. 1 diagrammatically shows a first example of a device in accordance with the invention,

10 Fig. 2 diagrammatically shows an exit opening with a series of detectors of the device in accordance with Fig. 1,

Fig. 3 diagrammatically shows one of the detectors in accordance with Fig. 2,

Fig. 4 diagrammatically shows a detector of a second example of a device in accordance with the invention, and

15 Fig. 5 diagrammatically shows a third example of a device in accordance with the invention.

Fig. 1 diagrammatically shows a first example of a device 1 in accordance with the invention for treating skin by means of radiation, said device being a hair removing
20 device, in particular a laser epilation device, by means of which hairs present on the skin are removed for a comparatively long period of time or permanently by means of laser light. Said device 1 comprises a housing 3 with a handle 5, so that the device 1 is portable and can be placed on or moved over skin 7 to be treated. The housing 3 accommodates a radiation source, in particular a laser source 9 such as a diode laser, and an adjustable laser beam
25 manipulator 11 by means of which a laser beam 13 generated, in operation, by the laser source 9 can be positioned, via an exit opening 15 provided in the housing 3, on the skin 7 in an target position 16. In the example shown, the laser beam manipulator 11 comprises a first adjustable tilting mirror 17 and a second adjustable tilting mirror 19, which are both arranged at an angle of approximately 45° with respect to a flat skin contact element 21, in which the
30 exit opening 15 is situated and which, in the example shown, forms a bottom wall of the housing 3. By means of a first actuator 23 and a second actuator 25, the tilting mirrors 17 and 19, respectively, can be tilted about, respectively, a first tilt axis 27, which extends in the plane of the first tilting mirror 17 and is directed substantially parallel to the second skin contact element 21, and a second tilt axis 29, which extends in the plane of the second tilting

mirror 19 and intersects the first tilt axis 27 substantially perpendicularly. By tilting the two tilting mirrors 17 and 19, the target position 16 of the laser beam 13 can be displaced over the skin 7 in a direction parallel to an X-direction and a Y-direction extending perpendicularly thereto, both directions being parallel to the skin contact element 21.

5 To determine successive target positions, the device 1 is provided, in the example shown, with an image sensor 31, such as a CCD image sensor or CMOS image sensor, which records an image of the part of the skin 7 that is situated directly in front of the exit opening 15, by means of an auxiliary lamp 33 and a transparent mirror 35. The device 1 further comprises a control unit 37 to which the image sensor 31 supplies an electrical signal
10 u_s which corresponds to the image recorded by the image sensor 31. The control unit 37 comprises a sensor by means of which, on the basis of the image recorded, the positions of the hair roots 39 of the hairs 41 present on said part of the skin 7 are determined on said part of the skin 7. The control unit 37 controls the two actuators 23 and 25 by means of, respectively, an electrical signal u_{M1} and an electrical signal u_{M2} , in such a manner that the
15 laser beam 13 is successively positioned in a series of target positions that correspond to the positions of the hair roots 39 thus determined. In each target position 16, the laser beam 9 is activated, during a predetermined period of time and with a predetermined intensity, by the control unit 37 by means of an electrical signal u_L , so that the hair roots 39 present are successively heated and die. For a detailed explanation of the operation of the device 1,
20 which is only briefly described herein, reference is made to WO-A-00/62700.

The laser beam 13 generated by the laser source 9 has a comparatively high intensity and hence is harmful when it contacts, for example, the eye. The device 1 in accordance with the invention is provided with means that can be used to prevent, to the extent possible, that the laser source 9 can be activated if the exit opening 15 is not, or not
25 completely, covered and enclosed by human skin, or if the exit opening 15 is covered with a medium other than human skin, such as glass. The reliability of said means is very high, so that the device 1 in accordance with the invention can particularly suitably be employed in the consumer market by inexperienced persons that are not skilled in the art. As shown in Fig. 1 and Fig. 2, said means comprise a series of detectors 43 which are provided in the skin
30 contact element 21 near the exit opening 15. In the example shown, said means comprise eight detectors 43 which are arranged at small, regular distances from each other around the exit opening 15. The detectors 43 can suitably be used to measure a biophysical property by means of which the human skin can be characterized. In the example shown, said biophysical property is the scattering coefficient and/or the absorption coefficient of the skin 7 for light of

a predetermined wavelength. As shown in Fig. 3, the detectors 43 of the example shown each comprise two light sources 45, 47 for light having two different, predetermined wavelengths, in the example shown two LEDs, and a single light sensor 49, in the example shown a photosensor, which is arranged next to the light sources 45, 47. The light sources 45, 47 and the light sensor 49 are each arranged in a separate chamber 51, 53, 55 of the detector 43, as a result of which the light sensor 49 is optically separated from the light sources 45, 47, i.e. light from the light sources 45, 47 cannot directly reach the light sensor 49. As shown in Fig. 3, light beams 57, 59 from the light sources 45, 47, on the other hand, are capable of reaching the light sensor 49 through scattering in the skin 7. To make sure that a substantial part of the light beams 57, 59 from the light sources 45, 47 can reach the light sensor 49, the light sources 45, 47 and the light sensor 49 must be in direct contact with the skin 7. The detector 43 further comprises an electrical circuit 61 that successively activates both light sources 45, 47 for a short period of time by means of two electrical signals u_{LED1} and u_{LED2} . As a result, the circuit 61 receives two successive electrical signals u_{PD1} and u_{PD2} from the light sensor 49 which correspond to the amounts of light that the light sensor receives through scattering in the skin 7 from, respectively, the two light sources 45 and 47. The circuit 61 subsequently determines the values of the scattering coefficient and/or the absorption coefficient of the skin 7 for the two different wavelengths of the two light sources 45, 47 by comparing the amounts of light received with the amounts of light generated by the light sources 45, 47, which amounts of light are determined by the signals u_{LED1} and u_{LED2} . The circuit 61 converts the values of the scattering coefficient and/or absorption coefficient thus measured into an electrical signal u_{CO} . As shown in Fig. 1, the electrical signals u_{CO} of all detectors 43 are received by the control unit 37 of the device 1. The control unit 37 comprises a comparator, not shown in the Figures, which compares the measured values of the scattering coefficient and/or absorption coefficient with values for the scattering coefficient and/or absorption coefficient that are characteristic of human skin and that are stored in a memory of the control unit 37. The control unit 37 can only activate the laser source 9 if the values measured by all detectors 43 correspond, within predetermined limits, to human skin-characteristic values, i.e. if all detectors 43 detect the presence of human skin. As shown in Fig. 3, the light sources 45, 47 and the light sensor 49 are arranged in the chambers 51, 53, 55, respectively, in such a manner that the light sources 45, 47 and the light sensor 49 only contact the skin 7 if the skin contact element 21 contacts the skin 7 at the location of the relevant detector 43, i.e. if there is no opening between the skin contact element 21 and the skin 7. In this manner it is achieved that the detectors 43 can also detect whether the skin contact element 21 fully

contacts the skin 7. If, at the location of one of the detectors 43, the skin contact element 21 is not in contact with the skin 7, then the light sources 45, 47 and/or the light sensor 49 of the relevant detector 43 are not in contact with the skin, as a result of which the amounts of light originating from the light sources 45, 47 and reaching the light sensor 49 are substantially reduced and the values of the scattering coefficient and/or absorption coefficient measured by the light sensor do not correspond, within the predetermined limits, with the human skin-characteristic values. As the control unit 37 can only activate the laser source 9 if all detectors 43 detect the presence of human skin against the skin contact element 21, a very reliable protection of the device 1 is provided against accidental or deliberate emission of the laser beam 13 via the exit opening 15. As a series of detectors 43 is used around the exit opening 15, the laser source 9 can only be activated if the exit opening 15 is completely covered. If the exit opening 15 is only partly covered, at least one of the detectors 43 does not detect the skin 7, as a result of which the laser source 9 cannot be activated. The laser source 9 cannot be activated either if the device 1 is obliquely arranged on the skin 7 or at a short distance from the skin 7, because, in this case, at least one of the detectors 43 is not in contact with the skin 7. The laser source 9 cannot be activated either if the medium present in front of the exit opening 15 is not human skin. In human skin, light is scattered and absorbed in a very characteristic way as a function of the wavelength of the light, which can be attributed to the presence of various components such as blood, water, cells, keratin and melanin. By means of the detectors 43, the values of the scattering coefficient and/or absorption coefficient are measured for two different wavelengths of the light, green light in the example shown, which has a comparatively short wavelength, and red light, which has a comparatively long wavelength. The combination of the values of these coefficients for said two types of light is very specific in human skin, so that this enables human skin to be characterized in a substantially unique way and the detectors 43 can detect the presence of human skin against the skin contact element 21 with a very high degree of certainty. If the exit opening 15 is covered with a different medium, such as glass, transparent synthetic resin or paper, the detectors 21 detect different values of these coefficients, so that the control unit 37 cannot activate the laser source 9.

It is to be noted that instead of eight detectors 43, a different number of detectors can be applied in the device 1. A reasonable degree of protection is already achieved if only one detector 43 is provided in the skin contact element 21 near the exit opening 15. Preferably, however, the device comprises at least two detectors 43 which are arranged at some distance from each other near the exit opening 15, for example on either

side of the exit opening 15, so that also a reasonable degree of protection is achieved in situations where the exit opening 15 is covered only partly. It is further noted that instead of the detectors 43, it is alternatively possible to use detectors by means of which the scattering coefficient and/or absorption coefficient for only one value of the wavelength of the light is measured. As light is scattered and absorbed in a very characteristic way in the human skin as a function of the wavelength, a very reliable detection can already be achieved by carrying out a measurement at only one predetermined wavelength. The invention also comprises embodiments, however, in which the detectors carry out measurements for three or more values of the wavelength. It is further noted that the structure of the detectors 43 is simple, which can be attributed to the fact that the light sensor 49 is used for both light sources 45, 47. The invention also comprises embodiments, however, wherein a separate light sensor is used for each light source 45, 47, which light sensor, for example, is sensitive only to light of the wavelength of the associated light source. It is further noted that the two light sources 45, 47 in the detector 43 are arranged on one side of the light sensor 49. This has the advantage that the light from the two light sources 45, 47 reaches the light sensor 49 by scattering of the light in the same part of the skin 7, so that the accuracy of the detector 43 is improved. Acceptable results are also achieved, however, in an alternative embodiment of the device in accordance with the invention, wherein the light sources 45, 47 are arranged on both sides of the light sensor 49. The LEDs and photosensors employed in the detectors 43 are comparatively inexpensive and have small dimensions, so that the cost price and the dimensions of the detectors 43 are limited. The invention also comprises embodiments wherein a different type of light source and/or a different type of light sensor is employed in the detectors 43. It is further noted that the invention also includes embodiments wherein, unlike the example shown in Fig. 3, the circuits 61 do not form part of the detectors 43 but of the control unit 37.

As shown in Fig. 1, a second example of a device 1' in accordance with the invention is substantially identical to the above-described device 1 in accordance with the first example. The device 1' differs mainly from the device 1 in that the device 1' is provided with eight detectors 63, instead of eight detectors 43, which detectors 63 can suitably be used to measure a reflection coefficient of the skin 7 with respect to light of a predetermined wavelength. Therefore, in the following description only the detectors 63 of the device 1' will be discussed, one of said detectors being diagrammatically shown in Fig. 4. As shown in Fig. 4, the detectors 63 each comprise, in the example shown, two light sources 65, 67 for generating light of two different, predetermined wavelengths. In the example shown said

light sources are two LEDs. The detector 63 further comprises a single light sensor 69, i.e. a photosensor in the example shown, which is arranged between the two light sources 65, 67. The light sources 65, 67 and the light sensor 69 are each provided in a separate chamber 71, 73, 75, respectively, of the detector 63, as a result of which the light sensor 69 is optically
5 separated from the light sources 65, 67. As shown in Fig. 4, light beams 77, 79 from the light sources 65, 67 can reach the light sensor 69 through reflection via the surface of the skin 7. The detector 63 further comprises an electrical circuit 81 which successively activates the two light sources 65, 67 for a short period of time by means of two electrical signals u'_{LED1} and u'_{LED2} . As a result, the circuit 81 successively receives two electrical signals u'_{PD1} and
10 u'_{PD2} from the light sensor 69, which electrical signals correspond to the amounts of light received by the light sensor 69 from, respectively, the two light sources 65 and 67 through reflection via the skin 7. The circuit 81 subsequently determines the values of the reflection coefficient of the skin 7 with respect to the two different wavelengths of the light sources 65 and 67 by comparing the amounts of light received with the amounts of light generated by the
15 light sources 65, 67, which amounts of light are determined by the signals u'_{LED1} and u'_{LED2} . The circuit 81 converts the values of the reflection coefficient thus measured into an electrical signal u'_{CO} which, as shown in Fig. 1, is received by the control unit 37 of the device 1'. The control unit 37, which compares the measured values of the reflection coefficient with values stored in a memory thereof, which are characteristic of human skin,
20 can only activate the laser source 9 if the values measured by all detectors 63 correspond, within predetermined limits, to the human skin-characteristic values, i.e. if all detectors 63 detect the presence of human skin. As light is reflected by the human skin in a very characteristic way as a function of the wavelength of the light, it is reliably determined by the detectors 63 whether the medium present directly in front of the exit opening 15 actually is
25 human skin. In the example shown, this reliability is substantially further improved in that the detectors 63 measure the reflection coefficient for two different values of the wavelength, i.e. in this example for yellow light having a comparatively short wavelength and for red light having a comparatively long wavelength. As shown in Fig. 4, the light sources 65, 67 and the light sensor 69 are at a predetermined distance d from the surface of the skin 7 only if the
30 skin contact element 21 is in contact with the skin 7 at the location of the relevant detector 63. The amounts of light received by the light sensor depend on the distance between the light sources 65, 67 and the skin 7 and on the distance between the light sensor 69 and the skin 7, and they decrease particularly substantially if the skin contact element 21 is not in contact with the surface of the skin 7, in which case an amount of light from the light sources

65, 67 can escape via the space present between the skin contact element 21 and the skin 7. Therefore, in order to achieve that the values of the reflection coefficient measured by the detectors 63 correspond, within predetermined limits, to the human skin-characteristic values, the exit opening 15 should, on the one hand, actually be covered by human skin and, on the other hand, the skin contact element 21 should be in contact with the surface of the skin 7. It is noted, however, that the reliability with which the detectors 63 can determine the presence of the skin 7 against the skin contact element 21 is smaller than the reliability with which the detectors 43 of the device 1 can determine the presence of the skin against the skin contact element. It is further noted that the invention also comprises modifications of the detectors 63 and of the number and positions thereof, such as the modifications of the detectors 43 described hereinabove.

The above-discussed detectors 43 and detectors 63 of, respectively, the device 1 and the device 1' in accordance with the invention can suitably be used to measure, respectively, the scattering coefficient and/or absorption coefficient of the skin and the reflection coefficient of the skin. It is noted that the invention also comprises embodiments wherein use is made of a detector which is suitable for measuring a different biophysical property by means of which the skin can be characterized, and wherein the comparator of the control unit can suitably be used to compare a value or condition of said property, measured by means of said detector, with a skin-characteristic value or condition of said property. An alternative biophysical property is, for example, the electrical resistance of the skin. This property is less reliable, however, than the above-described properties because the electrical resistance of the skin is influenced by the presence of moisture and additives on the skin. Another conceivable biophysical property is the presence of blood. The flow of blood in the skin is, for example, detectable by means of a laser-doppler measurement, and the resultant measuring signals are very characteristic of human skin. The sensors and processors necessary are more expensive, however, than the light sources and light sensors used in the above-discussed detectors 43 and 63. Other techniques that can suitably be used in a device in accordance with the invention for detecting the presence of skin are skin-imaging techniques, such as optical coherence tomography, confocal microscopy, two-photon microscopy and spectroscopic techniques. These techniques are very reliable, but owing to their complexity they are less suitable for use in devices for the consumer market, and more suitable for use in devices for the professional market.

The above-discussed devices 1 and 1' in accordance with the invention are laser epilation devices. The invention, however, also comprises other types of hair removing

devices, wherein hairs are shortened or removed by means of radiation issuing from an exit opening. An example of such a hair removing device is a laser shaver. The operation of such a laser shaver is basically the same as that of the above-discussed laser epilation devices, however, the target position of the laser beam is not in the hair root but in a position on the hair just above the surface of the skin. Another type of hair removing device, to which the invention may, for example, be applicable is a flashlight epilation device. The third example of a device 83 in accordance with the invention, as shown in Fig. 5, is an example of such a flashlight epilation device. The device 83 comprises a housing 85 wherein a frame 87 is arranged. Said frame 87 comprises a chamber 89 wherein a flashlight 91 is arranged as the radiation source, which is a xenon lamp in the example shown. The chamber 89 is filled with a cooling liquid for the flashlight, water being used as the cooling liquid in the example shown. The chamber 89 has a parabolically shaped wall 93, which is coated with a reflective material and hence serves as a reflector or directing element for the light generated by the flash light 91. The chamber 89 is shut off by a transparent plate 95, which, in the example shown, is a long-wave band pass filter. The device 83 further comprises an optical waveguide 97 which opens into an exit opening 99. Around the exit opening 99 there is provided a skin contact element 101 accommodating a number of detectors 103 of a type similar to the above-described detectors 43 or 63. In operation, the flash light 91 generates a series of light pulses having a predetermined pulse duration and intensity, which pulse duration and intensity may vary as a function of time. The light pulses are directed at the exit opening 99 by the wall 93 and reach the exit opening 99 via the transparent plate 95 and the optical waveguide 97. The frequency of the light pulses is such that the light pulses are absorbed, in particular, by the hair roots present in the skin, as a result of which the hair roots are heated and die. For a detailed explanation of the operation of the device 83, which is only briefly described herein, reference is made to EP-A-0 885 629. The flash light 91 can only be activated if all detectors 103 detect the presence of human skin against the skin contact element 101, i.e. if the exit opening 99 is completely covered by human skin.

The devices 1, 1' and 83 discussed hereinabove all are hair removing devices. It is noted that the invention also comprises other types of devices for treating skin by means of radiation. Examples of such devices are devices for the medical treatment of skin by means of radiation, such as by means of laser light, flashlights, or other types of radiation having a comparatively high intensity. Such devices are used, for example, for treating birthmarks, such as naevus pigmentosus and naevus vinosus, present on the skin, psoriasis, or

aberrations of blood vessels present in the skin. Other examples of such devices include devices for skin-rejuvenation cures by means of radiation.

It is finally noted that the invention also comprises devices wherein the detector or detectors are arranged in a position that differs from their position in the skin contact element of the device. A position of the detectors in the skin contact element near the exit opening, as in the above-discussed devices 1, 1' and 83, however, generally leads to an optimum protection of the device.

CLAIMS:

1. A device for treating skin by means of radiation, which device comprises a housing, which accommodates a radiation source and which is provided with an exit opening for the radiation, a detector for detecting the presence of skin directly in front of the exit opening, and a control unit which activates the radiation source only if the detector detects the presence of skin directly in front of the exit opening, characterized in that the detector can suitably be used to measure a biophysical property by means of which the skin can be characterized, the control unit comprising a comparator for comparing a value or condition of the property, measured by means of said detector, with a skin-characteristic value or condition of the property.
2. A device as claimed in claim 1, characterized in that the housing comprises a skin contact element in which the exit opening is formed and in which said detector is provided near the exit opening.
3. A device as claimed in claim 2, characterized in that a series of detectors is provided in the skin contact element around the exit opening to measure the biophysical property.
4. A device as claimed in claim 1, characterized in that the detector can suitably be used to measure a scattering coefficient and/or an absorption coefficient of the skin for light of a predetermined wavelength.
5. A device as claimed in claim 2 and claim 4, characterized in that the detector is provided with a light sensor and a light source for light of said predetermined wavelength, which light source is arranged next to the light sensor and optically separated from said light sensor, the light source and the light sensor being in contact with the skin only if the skin contact element is in contact with the skin, and the detector determining the scattering coefficient and/or absorption coefficient by comparing an amount of light measured by the light sensor with an amount of light generated by the light source.

6. A device as claimed in claim 5, characterized in that the detector is provided with a further light source for light of a further, predetermined wavelength, which light source is also arranged next to the light sensor, optically separated from said light sensor and in contact with the skin only if the skin contact element is in contact with the skin, the detector determining the scattering coefficient and/or absorption coefficient for both wavelengths by comparing the amounts of light measured by the light sensor with the amounts of light generated by the two light sources.

7. A device as claimed in claim 6, characterized in that the light source and the further light source are arranged on one side of the light sensor.

8. A device as claimed in claim 5, characterized in that the light source is a LED, and the light sensor is a photodiode.

9. A device as claimed in claim 1, characterized in that the detector can suitably be used to measure a reflection coefficient of the skin for light of a predetermined wavelength.

10. A device as claimed in claim 2 and claim 9, characterized in that the detector is provided with a light sensor and a light source for light of said predetermined wavelength, which light source is arranged next to the light sensor and optically separated from said light sensor, the light source and the light sensor being situated at a predetermined distance from the skin only if the skin contact element is in contact with the skin, and the detector determining the reflection coefficient by comparing an amount of light measured by the light sensor with an amount of light generated by the light source.

11. A device as claimed in claim 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10, characterized in that the device is a hair removing device, wherein the radiation source comprises a laser source, and the device is further provided with an adjustable laser beam manipulator for positioning a laser beam supplied, in operation, by the laser source in a target position on the skin to be treated.

12. A device as claimed in claim 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10, characterized in that the device is a hair removing device, wherein the radiation source comprises a flashlight for generating light pulses, and the device is further provided with a directing element for directing the light pulses to the exit opening.

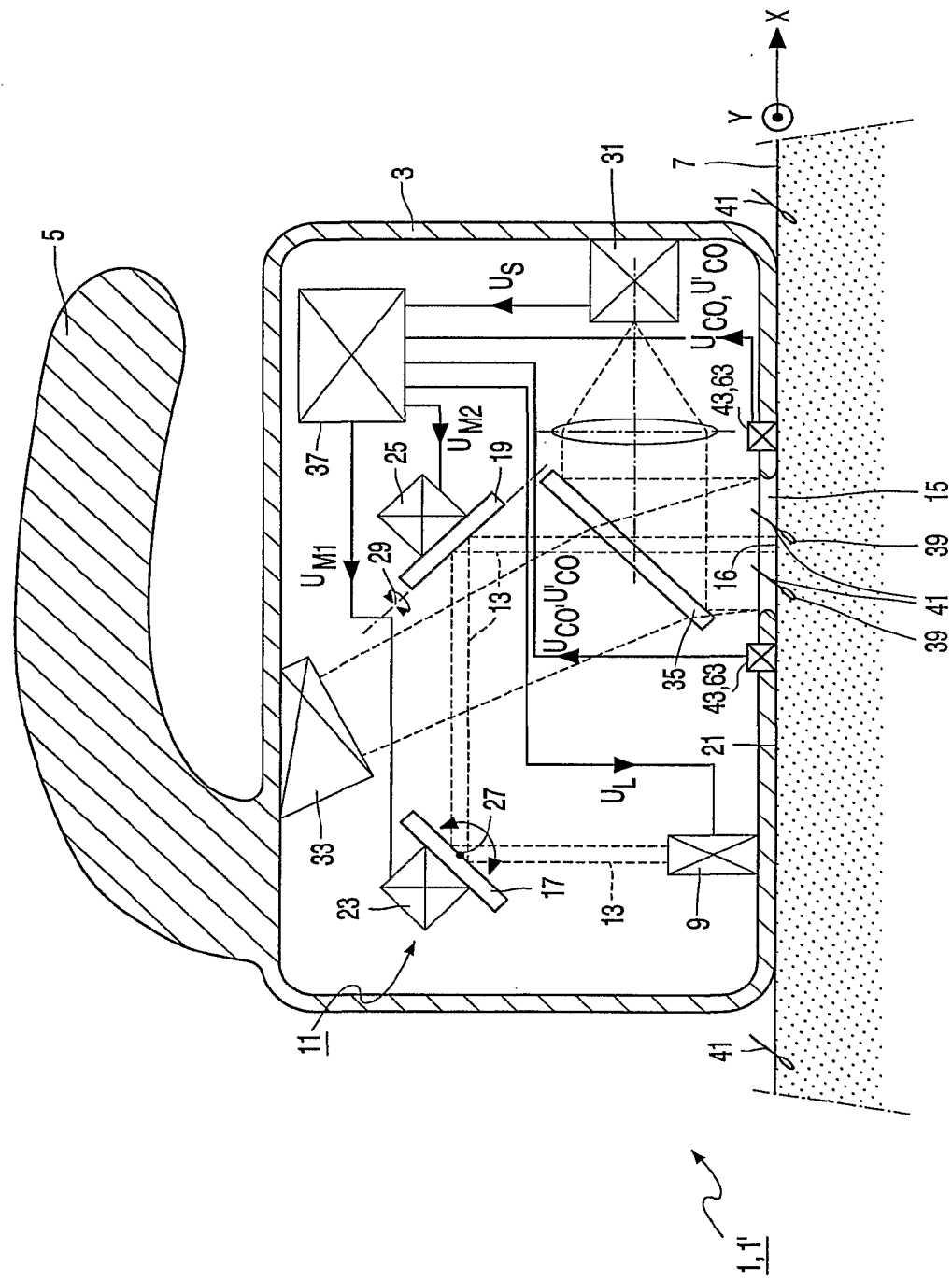


FIG. 1

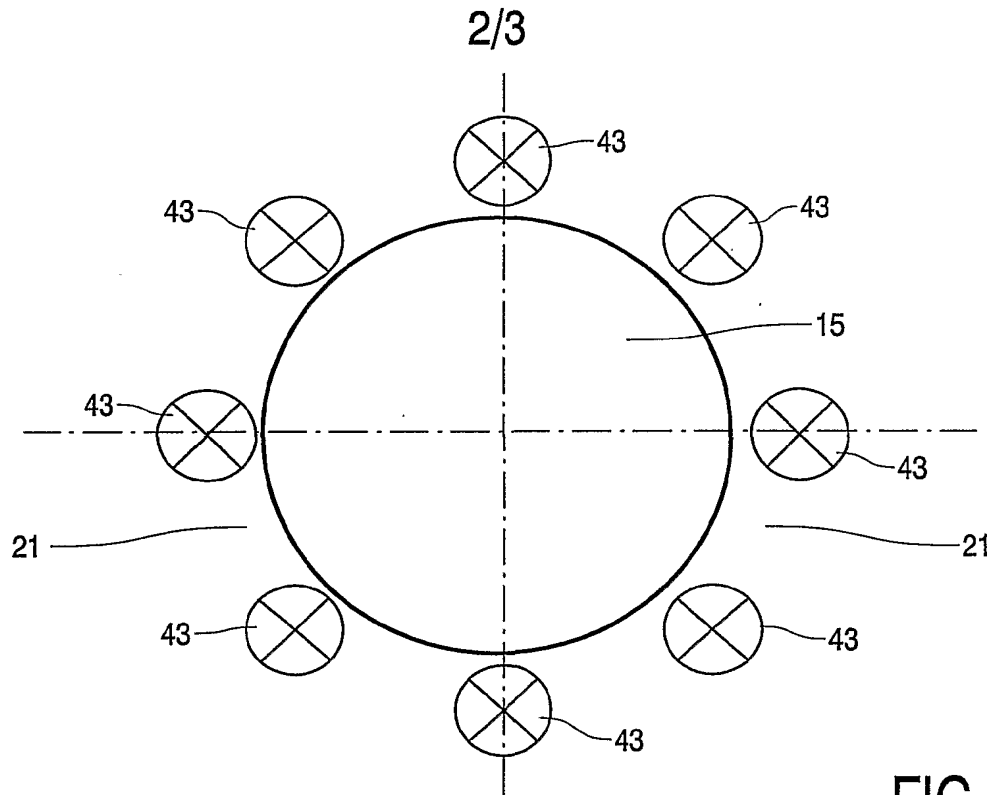


FIG. 2

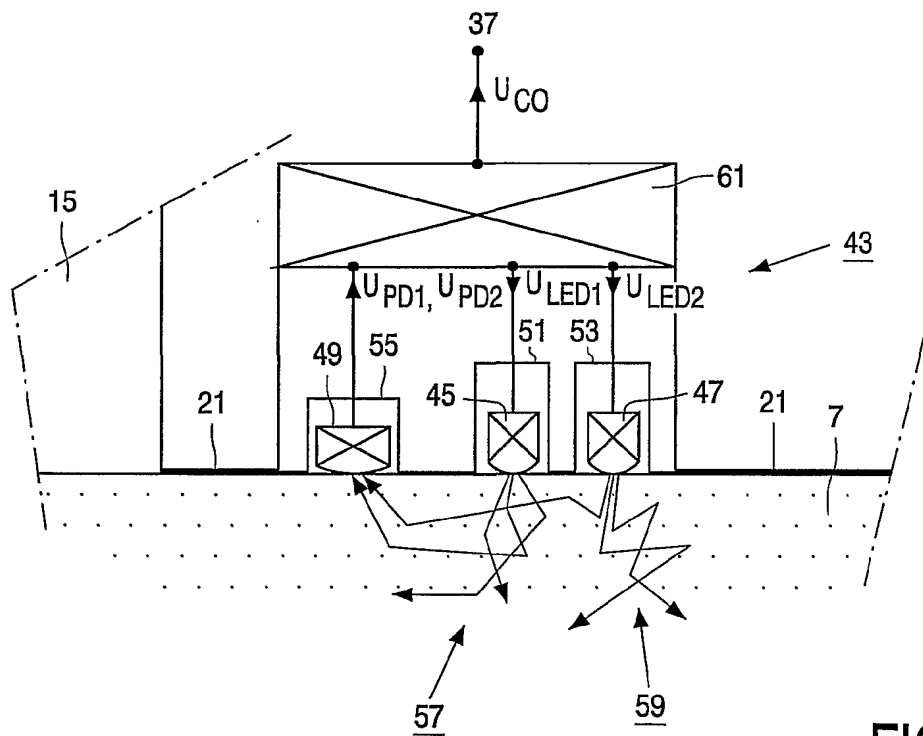
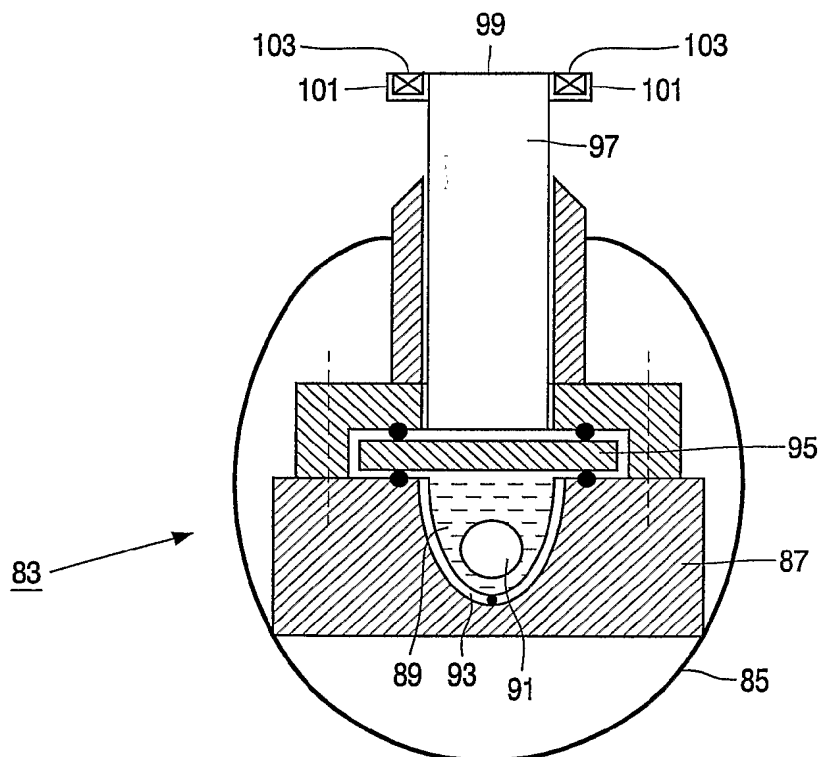
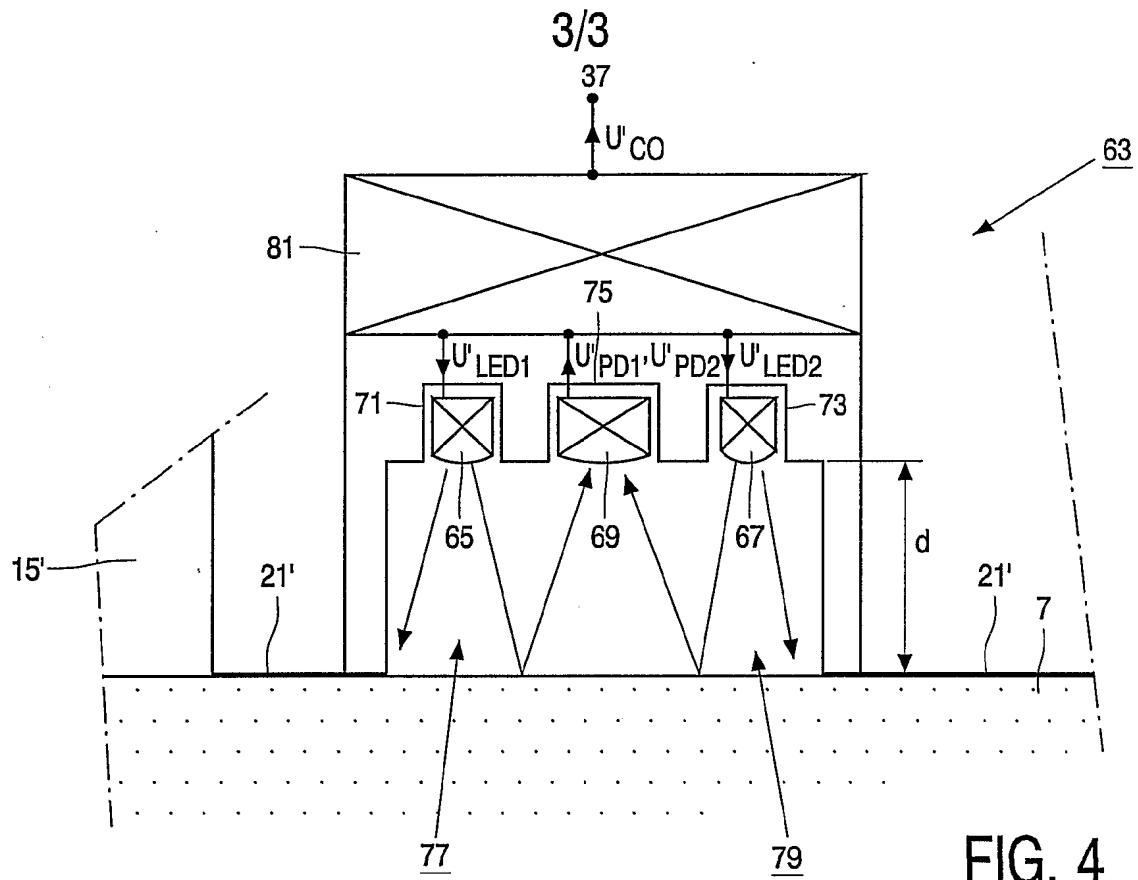


FIG. 3



INTERNATIONAL SEARCH REPORT

Inter Application No

PCI/IB 02/00641

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 01 26573 A (COHERENT INC) 19 April 2001 (2001-04-19) page 5, line 23 -page 6, line 23 page 22, line 9 - line 33 page 28, line 11 -page 30, line 6; figure 15 ---	1-5,8-12
X	US 5 501 680 A (NARAYANAN KRISHNA ET AL) 26 March 1996 (1996-03-26) column 5, line 66 -column 6, line 18 column 7, line 24 - line 54 column 8, line 14 - line 25 ---	1-5,8-10
X	US 6 074 382 A (BALLE-PETERSEN OLAV ET AL) 13 June 2000 (2000-06-13) column 4, line 27 -column 5, line 53 ---	1-11
Y	---	12
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents:

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 07379 A (LARSEN ERIC ;HOEGSETH SOLFRID (NO)) 26 February 1998 (1998-02-26) claims 8-10 ----	12
X	EP 1 057 454 A (NIDEK KK) 6 December 2000 (2000-12-06) column 1, line 56 -column 3, line 49 column 10, line 51 -column 11, line 4 column 11, line 40 -column 12, line 11 ----	1,2,11
A	PATENT ABSTRACTS OF JAPAN vol. 017, no. 364 (C-1081), 9 July 1993 (1993-07-09) & JP 05 057026 A (MATSUSHITA ELECTRIC IND CO LTD), 9 March 1993 (1993-03-09) cited in the application abstract ----	1
A	WO 00 62700 A (KONINKL PHILIPS ELECTRONICS NV) 26 October 2000 (2000-10-26) cited in the application abstract ----	1
A	EP 0 885 629 A (DANISH DERMATOLOGIC DEV A S) 23 December 1998 (1998-12-23) cited in the application column 7, line 40 - line 53 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter I Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0126573	A	19-04-2001	WO 0126573 A1	19-04-2001
US 5501680	A	26-03-1996	NONE	
US 6074382	A	13-06-2000	AU 8851898 A	22-03-1999
			WO 9911324 A1	11-03-1999
			EP 1009485 A1	21-06-2000
			JP 2001514057 T	11-09-2001
			US 6383177 B1	07-05-2002
WO 9807379	A	26-02-1998	AU 4225897 A	06-03-1998
			EP 0959788 A1	01-12-1999
			NO 990658 A	09-04-1999
			WO 9807379 A1	26-02-1998
EP 1057454	A	06-12-2000	JP 2000334053 A	05-12-2000
			JP 2001314418 A	13-11-2001
			JP 2001314419 A	13-11-2001
			EP 1057454 A2	06-12-2000
			US 2001007068 A1	05-07-2001
JP 05057026	A	09-03-1993	NONE	
WO 0062700	A	26-10-2000	WO 0062700 A1	26-10-2000
			EP 1087716 A1	04-04-2001
EP 0885629	A	23-12-1998	EP 0885629 A2	23-12-1998

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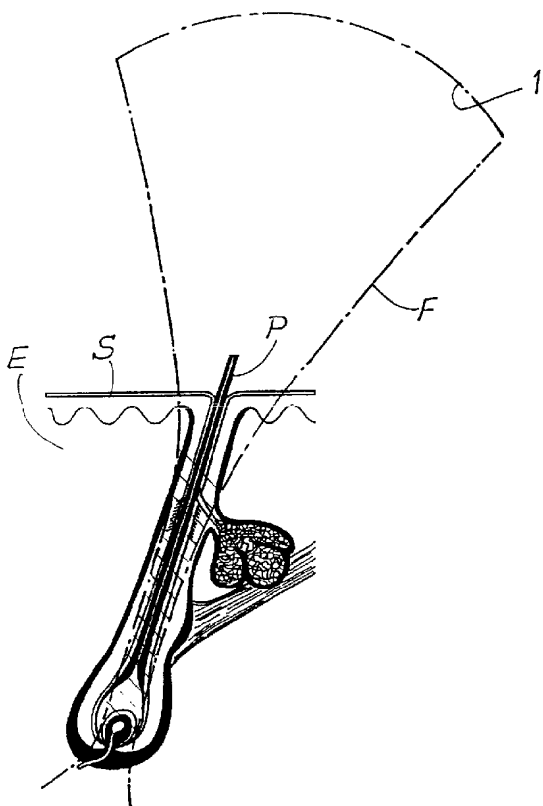
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(54) Title: METHOD AND DEVICE FOR EPILATION BY ULTRASOUND



(57) Abstract: A description is given of a method of hair removal, characterized in that ultrasonic waves (F) are applied to a hair follicle until a rise in temperature is caused as a result of the absorption of said ultrasonic waves by the tissues, this temperature rise being sufficient to cause damage to the hair follicle.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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Method and device for epilation by ultrasound

DESCRIPTIONTechnical field

The present invention relates to an epilation method and a device
5 for the application of said method.

Prior art

At the present time, techniques for removing superfluous hair are
not only applicable to women with problems of hirsutism or hypertrichosis, but
are commonly used on subjects of both sexes, not necessarily because they
10 are suffering from particular pathologies, but purely for aesthetic reasons. The
processes commonly used for this purpose can be classified in terms of the
permanence of the results.

Thus there are short-term systems (such as razors, tweezers, hot
and cold waxing, creams, gels and electric hair removers) and long-term
15 systems which can sometimes yield permanent results after a certain number
of sessions. Some examples of methods and devices relating to this second
group of epilation techniques are needle-type electrocoagulators, needles with
radio knives, non-coherent light and lasers.

Among the long-term treatment methods, the greatest success has
20 been achieved by the use of laser systems which are based on the theory of
selective photothermolysis and are able to damage the hair bulb by means of
the laser energy absorbed by the melanin present in the hair or by the
hemoglobin in the bulb blood vessels, in a ratio which depends on the
wavelength of the laser used. This method is described in Anderson R.,
25 Parrish J: "The optics of human skin", J. Invest. Dermatol. 1981, 77:13-19, and
in Parrish J., Anderson R. et al.: "Selective thermal effect with pulsed
irradiation from lasers: from organ to organelle", J. Invest. Dermatol. 1983,
80:75s-80s;

In spite of the excellent results, limitations of this epilation
30 treatment are encountered in the treatment of subjects with white hair or dark
skin. In the first case, the hairs have a low melanin content, making the
absorption of the laser radiation by the hair very limited, and therefore it is not

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possible to make a significant contribution to the raising of the temperature of the hair bulb and thus damage it. In the second case, on the other hand, practically all of the radiation is absorbed by the skin (which, being dark, has a high melanin content) with the possibility of causing potentially irreversible damage to the subject's skin.

Laser epilation systems are more effective when they are applied to the hair in the anagen growth phase. This is because hair growth is not continuous but cyclical: a resting period, known as telogen, follows each growing period known as anagen; the period of transition between the two phases is known as catagen. The length of the cycle varies between areas of hair growth, from 2-6 years for the head hair to only 4-8 weeks for the eyebrows. According to current biological models, the cells which generate the follicle are located in what is known as the bulge area. These cells form the new matrix of the hair, thus initiating the growth phase. At the start of this phase, when the follicle is shorter, the papilla is closer to the skin surface; subsequently it extends to a greater depth and proliferates for a period varying according to the anatomical location. It is in the initial phase of anagen, or anagen 1, that the "target" structures of the follicle (such as the papilla and the bulge area), with their vascular system, are closer to the hair and to the surface of the epidermis; the closer the papilla and the tip of the hair, the greater is the probability that the laser energy absorbed by the melanin of the hair, and that arriving directly, will succeed in irreparably damaging the papilla, thus permanently blocking its capacity to make a hair grow. This shows clearly why the action of a laser is more effective in the anagen phase.

Objects and brief description of the invention

The object of the present invention is to provide a method and a device for long-term epilation which have a high efficacy and are not affected by the limitations of laser systems. More particularly, the object of the present invention is to provide a device and a method which can be used effectively even on subjects having a skin with a high melanin content and/or on subjects with white hair. A further object is to provide a method and a device whose efficacy is independent of the growing phase of the hair.

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These objects are achieved, according to the present invention, by the use of an energy source which is not affected by the color of the hair or that of the skin: namely mechanical energy carried by ultrasonic waves.

These and other objects and advantages, which the following text
5 will make clear to those skilled in the art, are obtained according to the present invention by means of an apparatus and a treatment method which use ultrasounds as the energy source for the removal of superfluous hairs.

The method according to the invention is thus characterized in that an
10 area from which hair is to be removed is struck with ultrasonic waves until the temperature of the tissues is raised - as a result of the absorption of the energy carried by the ultrasonic wave - to a degree sufficient to cause damage to the hair follicle.

The term "ultrasounds" denotes a particular type of elastic
mechanical waves (ultrasound or ultrasonic waves), characterized by a
15 frequency of more than 20 kHz. These are successive waves of rarefaction and compression of the particles of each medium through which the waves pass, which are propagated longitudinally within the medium. The displacement of each particle of the medium within which the ultrasonic wave is transmitted is of the order of very small fractions of a millimeter, while the
20 perturbation extends for several centimeters into the medium.

Ultrasonic waves can advantageously be generated by exploiting
the phenomenon of piezoelectricity, a characteristic of certain materials such as quartz, barium titanate, lead titanate zirconate or polymers such as polyvinyl fluoride. The application of a potential difference to the ends of a
25 plate made from these materials causes a dimensional change in the plate (the inverse piezoelectric effect). The frequency at which a plate of these materials, called a transducer, starts to vibrate when it is activated by a potential difference is called the resonant frequency, and is typically related to the thickness of the plate.

30 The width of a beam of ultrasonic waves is a function of the size of the transducer, the frequency, the material in which the propagation takes place, and the focusing of the beam. The last of the three cited parameters is

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the most important. There are different ways of focusing an ultrasound beam: the use of an intrinsically focused plate, the interposition of acoustic lenses between the surface of the transducer and the tissues, and electronic focusing. All these procedures tend to achieve the same result of making the beam converge toward an area of space located at a certain desired distance from the interface between the ultrasonic transducer and the propagation medium of the ultrasonic waves.

In the case of the application to which the present invention relates, it is advantageous to arrange for the ultrasonic beam to be focused at a suitably selected depth with respect to the external surface of the skin, so that at this level (the focal plane) the diameter of the beam is as small as possible. This makes it possible to achieve a high density of energy carried by the ultrasonic waves and to strike with this energy only the desired target, in other words the tissues surrounding the hair follicle which is to be destroyed.

The intensity of the ultrasonic beam decreases progressively as it advances into the tissues. The phenomenon is closely dependent on the frequency of the beam in question, and is due to four different factors: reflection, diffusion, widening of the beam and absorption. The factor most relevant to the present invention is the phenomenon of energy absorption by the tissues through which the beam passes, with a conversion of the beam to heat and a consequent increase in temperature in the treated area. When the temperature of the soft tissue reaches approximately 65°C, the phenomenon known as protein denaturing occurs, with consequent necrosis of the tissue. This principle is used to carry out transcutaneous surgical operations (for literature on this subject, see: "Acoustic parameters of high energy pulsed ultrasound (hepus) for experimental tissue destruction", by T. Dreyer, J. Zenk, R. Riedinger, T. Schneider, H. Iro, Ultrasound in Medicine and Biology, April 2000, 26(4) suppl B, PHO03; "Noninvasive monitoring of temperature distribution in the target field of hyperthermia by ultrasonic tissue characterization" by L. Zuna, P. Novak, L. Pousek, P. Schreib, P. Pesche, A. Lorenz, J. Debus, Ultrasound in Medicine and Biology, April 2000, 26(4) suppl B, PHO04; "Acoustic parameters of high energy pulsed ultrasound (hepus) for

- 5 -

experimental tissue destruction" by T. Dreyer, J. Zenk, R. Riedinger, T. Schneider, H. Iro, Ultrasound in Medicine and Biology, April 2000, 26(4) suppl B, PHO03; "Treatment of uterine fibroid tumors in eker rats using high intensità focused ultrasound" by S. Vaezy, M. Paun, P. Nelson, C. Walzer, V. Fujimoto, Ultrasound in Medicine and Biology, April 2000, 26(4) suppl B, PHO05; "A new treatment for miu controlled hifu therapy", by J. Jehne, R. Rastert, L. Simiantonakis, C. Bohris, J. Spoo, J. Debus, Ultrasound in Medicine and Biology, April 2000, 26(4) suppl B, PHO06).

In practice, according to the invention, use can be made of a transducer emitting ultrasonic waves capable of focusing the beam (or a transducer provided with auxiliary means of focusing the beam) in a precise and limited area of space. Advantageously, the focal zone of the beam has a pseudo-cylindrical shape with a circular directrix and segments on the generatrices having dimensions a few times greater than the diameter of the circle subtended by the directrix.

By using frequencies in the range from a few hundred kHz to a few MHz, and typically from 100 kHz to 10 MHz, it is possible to obtain a focal spot with lateral dimensions which may be up to a few tenths of the millimeter and a longitudinal extension which may be a few millimeters. A sufficient ultrasonic energy creates a necrosis in a "carrot"-shaped volume of tissue which comprises the hair follicle. Because the volume affected by the raising of the temperature is small, the necrosis of the follicle can be achieved with minimal damage, or none at all, to the surrounding tissues.

The small dimensions of the focal spot make it appropriate to use optical magnifying systems which enable the operator to emit the ultrasonic energy when the hair and the surrounding structures have been identified by means of a suitable aiming system. The use of a relatively long focal zone means that a lack of knowledge of the depth at which the hair is located is "not critical".

Further advantageous characteristics and embodiments of the method according to the invention are indicated in the attached claims.

The invention also relates to an epilation device characterized in

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that it has a focused ultrasonic beam generator. The ultrasonic generator can consist of an ultrasonic transducer, for example an intrinsically focused transducer, or an array of transducers. Alternatively, the generator can comprise an ultrasonic transducer and other components, for example
5 focusing means, which in combination with the transducer generate a focused beam.

A different way of constructing the ultrasonic generator requires the use of a fiber which is brought into position and through which a Q-switched laser radiation is transmitted, creating a mechanical shock and thus giving rise
10 to an ultrasonic wave. A transducer of this type is described in IT-A-1286836 and in further bibliographical references cited therein.

To obtain correct acoustic coupling, the transducer can be combined with a low-impedance means, for example a bag containing a gel or a liquid, for example water, which is interposed between the transducer and
15 the epidermis. This bag and the substance contained in it can advantageously be transparent or translucent to permit observation of the area to be treated.

The device can also be combined with magnifying means to facilitate the observation of the area to be treated, for example a micro-video camera or bundles of coherent fibers, connected to a monitor. To facilitate the
20 use of the device, it can be provided with suitable aiming means, for example an aiming beam, which can be an optical beam of white or colored light, or preferably a laser beam which can be guided toward the operating area by means of a light guide consisting of optical fiber or equivalent.

In a particularly advantageous embodiment of the device, means
25 can be provided to cool the area subjected to the epilation treatment, with the double purpose of causing the erection of the hair to facilitate its destruction by means of the acoustic beam, and preventing heat damage or disagreeable sensations of excessive heating due to the high energy density incident on the tissues. The cooling means can consist of cold air blowing systems or
30 possibly a system of cooling the substance contained in the bag, provided for the purpose of acoustic coupling, positioned between the ultrasonic transducer and the epidermis. It is also possible to include in the handpiece a

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small LCD monitor, of the type used in modern amateur video cameras, to be connected to the micro-video camera or to the bundle of coherent fibers, thus making it possible to view the portion of skin to be treated. If the user considers it more convenient, it is always possible to use an external monitor
5 (of the TV screen type) in place of the LCD type fitted on the handpiece.

The ultrasonic generator, the bag containing the substance for acoustic coupling, and any aiming and observation systems can be fitted in a handpiece which can easily be grasped by the operator.

Further possible advantageous characteristics of the device
10 according to the invention are indicated in the attached claims.

Brief description of the drawings

The invention will be more clearly understood from the description and the attached drawing which shows non-restrictive practical embodiments of the invention. In particular, in the drawing:

15 Fig. 1 shows the anatomical structure of the hair follicle and the operating principle of the system and method according to the invention;

Fig. 2 shows schematically a different procedure for obtaining a focused ultrasonic beam;

Fig. 3 shows schematically a longitudinal section through a
20 handpiece for the application of the method according to the present invention; and

Fig. 4 shows a front view according to IV-IV in Fig. 3.

Detailed description of an embodiment of the invention

Fig. 1 shows schematically the principle on which the present
25 invention is based. This figure shows a portion of epidermis E, whose external surface is indicated by S. P indicates a hair to be removed, with the corresponding follicle and the other anatomical structures, including the sebaceous gland and the erector muscle.

An ultrasonic transducer, for which the emission surface of the
30 wave front is indicated in a general way by 1, generates a focused ultrasonic beam F which has a focused zone of pseudo-cylindrical form under the surface S of the epidermis. The volume of this pseudo-cylindrical zone

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encloses the follicle of the hair P. Downstream from the follicle with respect to the direction of arrival of the wave front, the beam F widens.

In order to obtain the focusing of the ultrasonic beam, the transducer can be intrinsically focused, being in the shape of a portion of a hollow spherical bowl, as indicated schematically by the surface 1 in Fig. 1. However, this is not the only possible focusing method. Alternatively, a flat transducer with an acoustic lens which enables the beam to be focused (not illustrated) can be used. In a different embodiment, electronic focusing systems are used, which enables the distance of the focal spot to be varied as required.

Another possible embodiment, shown schematically in Fig. 2, makes use of a system formed by an array of ultrasonic transducers in the form of concentric rings, indicated schematically by 5A, 5B in Fig. 2. These transducers are aligned in phase, thus enabling the size of the lateral emission lobes (lobes L1 in Fig. 2) to be minimized, while the central emission lobes L2 are added to obtain focal spots which are very restricted laterally and cover a sufficient depth.

Regardless of the chosen focusing methods, by suitable design of the emitting surface of the transducer or of the array of transducers (which must have rather large dimensions, of the order of a few centimeters for example), and by using frequencies in the range from a few hundred kHz to several MHz, it is possible to focus the beam of ultrasound, thus providing a focal spot with a width of a few tenths of a millimeter and a length which may be a few millimeters, to cover a wide range of depths. The form of the ultrasonic beam will be such that the energy density in the surface region S of the skin (where the beam enters the tissues) will be low, while in the depth of the focal zone the energy density will be high. The ultrasound system which has been constructed produces a temperature rise in the tissues, due to their absorption of the ultrasound and the consequent conversion of the mechanical energy to thermal energy. When the temperature of approximately 65°C has been reached in the soft tissue, the process of protein denaturing starts and results in the necrosis of the tissue. If sufficient ultrasonic energy is

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used, a "carrot"-shaped necrosis is created in a volume of tissue extending from the epidermis and including the whole structure of the hair follicle, the papilla and the bulge area. Because the volume concerned is small, local hyperthermia can be obtained in a very small volume, restricted to the hair follicle alone, thus limiting, or even eliminating, any irreversible damage to the surrounding tissues.

During the various phases of growth of the hair, the position of the papilla and the bulge area vary within a range of several mm. The longitudinal dimension of the "carrot"-shaped volume within which the ultrasonic beam is focused is such that these structures are struck in all of their possible positions, so that the efficacy of the treatment no longer depends, as in the case of laser epilation, on the closeness of the papilla to the tip of the hair. The result can therefore be permanent, even if the hair is not in the anagen phase.

Figs. 3 and 4 show schematically an embodiment of an epilation device according to the invention. The device comprises a handpiece, indicated in a general way by 11, in which the ultrasonic transducer indicated by 13 is located. In this embodiment, the transducer is an intrinsically focused transducer, with an emission surface in the form of a concave spherical bowl, as shown schematically in Fig. 1.

The handpiece 11 is provided with a spacer 15, by means of which the focal zone of the ultrasonic beam is positioned at a short distance below the surface S of the skin (as shown in the diagram in Fig. 1), where the hair follicle is located. To facilitate the aiming of the ultrasonic beam, the handpiece 11 is associated with a light guide formed by a very low power laser 17 and an optical fiber 19 whose remote end opens approximately in the center of the spherical bowl forming the emission surface of the transducer 13. Thus a spot of light corresponding to the point of intersection of the axis of the focused ultrasonic beam is projected on to the surface S of the epidermis.

The handpiece is also associated with a micro-video camera 21, connected to a monitor 23, for displaying the skin which is to be treated, in such a way that the ultrasonic energy is released precisely at the position of a

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hair follicle, with the aid of the aiming system consisting of the laser 17 and the corresponding optical fiber 19. A light source 25 generates a beam of illumination of the area to be viewed, for correct operation of the micro-video camera 21. The light generated by the source 25 is guided to the treatment
5 area by means of a light guide 27 of the optical fiber type or the like.

The handpiece is provided with a bag 29 of flexible material, arranged so that it is located, during operation, between the transducer 13 and the skin. The bag 29, made from flexible and transparent or translucent material, contains water or a similar transparent substance which does not
10 attenuate the ultrasounds, to provide an acoustic coupling between the ultrasonic transducer 13 and the skin on which the treatment is to be carried out. The presence of this bag makes it possible to have an optimal distance between the transducer and skin for the correct positioning of the focal zone below the skin. It should be noted that air markedly attenuates ultrasounds, so
15 that it becomes important to use a means which reduces the coefficient of attenuation of the region lying between the transducer and the skin. The means used must be transparent to permit the operation of the optical magnifying systems (micro-video camera 21 and monitor 23 in the illustrated example) and of the aiming laser 17.

20 To further improve the transmission of ultrasounds while reducing the coefficient of attenuation of the means through which the ultrasonic waves are to pass, it is possible to arrange for a thin layer of transparent gel to be interposed between the bag 29 and the skin. Alternatively, the skin can be lightly bathed before the ultrasonic handpiece is passed over it.

25 To prevent the temperature rise produced by the ultrasonic impulse from causing pain or discomfort in the subject being treated, it is possible to use a skin cooling system of the cold air emission type during the treatment. By using a cooling system it is also possible to make the erector muscles of the hair contract, so that the hair is brought into a more perpendicular position
30 with respect to the skin surface. In this condition, it is easier to position the focused zone of the ultrasonic beam correctly in such a way that all the relevant areas (follicle, papilla and bulge area) are struck. Cooling of the cold

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air type is particularly useful where the substance contained in the bag 29 has a gelatinous consistency.

A different possible method of cooling the skin, which is particularly advantageous if the substance contained in the bag is very fluid (water, for example), consists in providing a system for directly cooling the substance contained in the bag 29. The contact of the external surface of the bag 29 with the surface layer of the skin cools the skin and causes the contraction of the erector muscles of the hair. A solution of this type is shown in the example illustrated in Figs. 3 and 4. The liquid in the bag 29 is guided by means of ducts 31 toward a heat exchanger 33 where there is provided an arrangement of tubes in which a fluid refrigerated by an external refrigerator unit 35 circulates, or a different arrangement for obtaining the forced cooling of the liquid in the bag 29.

As an alternative to the cooling system, when it is not necessary to provide cooling to prevent the risk of burns, it is possible to use any method which achieves the object of making the erector muscles of the skin contract.

The device indicated schematically in Figs. 3 and 4 is supplemented by a unit 37 for supplying and controlling the transducer 13.

Epilation is carried out as follows: the handpiece is grasped by the operator and brought with the bag 29 into contact with the skin of the subject to be treated, in the proximity of the individual hair to be removed. The bag is pressed against the external surface of the skin and the operator observes on the monitor 23 the area under the transducer 13 recorded by the micro-video camera 21. The spot of the aiming laser beam generated by the source 25, as well as the hair to be removed, will be visible in this area. The handpiece can thus be positioned by the operator so that the axis of the ultrasonic transducer 13 is made to intercept the skin at the position of the follicle, the interception point coinciding with a good approximation with the spot of the aiming laser beam. When the aiming has been carried out in this way, the ultrasonic transducer 13 is operated, for example by means of a push button on the handpiece 11 (not shown) or by means of a pedal control or other. The acoustic energy generated in this way is focused around the hair follicle, and

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the temperature of the tissues struck by the focused zone (which has a "carrot"-like or pseudo-cylindrical shape, as indicated above) is brought to a value sufficient to cause their necrosis.

The process is repeated for all the hairs which are to be removed.

- 5 Without restriction to specific values, which can vary from one case to another and which can easily be identified by the operator by a series of tests, pulses of ultrasonic waves suitable for destroying the hair follicle typically have the following characteristics: an acoustic energy per pulse in the range from 100 to 1200 mJ, and preferably from 120 to 250 mJ; and a pulse length
10 in the range from 15 to 200 ms, and preferably from 20 to 40 ms.

The beam is advantageously focused in such a way as to generate a focusing zone with a maximum transverse dimension of the order of 1 mm or preferably of the order of 0.5 mm or less, and with a longitudinal dimension of the order of 1-8 mm and preferably of the order of 2-4 mm.

- 15 It is to be understood that the drawing shows only an example provided solely as a practical demonstration of the invention, this invention being variable in its forms and arrangements without departure from the scope of the guiding principle of the invention. The presence of any reference numbers in the attached claims is intended to facilitate the reading of the
20 claims with reference to the description and to the drawing, and does not limit the scope of protection represented by the claims.

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CLAIMS

1. An epilation method, characterized in that ultrasonic waves are applied to a hair follicle until a rise in temperature is caused as a result of the absorption of said ultrasonic waves by the tissues, this temperature rise being
5 sufficient to cause damage to the hair follicle.

2. The method as claimed in claim 1, characterized in that a beam of ultrasound is generated and said beam is focused in the area surrounding the hair follicle.

3. The method as claimed in claim 1 or 2, characterized by
10 applying an ultrasonic energy capable of raising the temperature of the tissues of the hair follicle to a temperature equal to or greater than the temperature at which the proteins of said tissues are denatured.

4. The method as claimed in claim 3, characterized in that the temperature of said tissues is raised above 60°C and preferably to
15 approximately 65°C.

5. The method as claimed in one or more of the preceding claims, characterized in that a focusing volume of the ultrasonic beam is generated with an elongate shape which penetrates from the skin surface toward the interior of the underlying tissues, the area of greater energy density of the
20 focused ultrasonic beam being under the skin surface.

6. The method as claimed in one or more of the preceding claims, characterized in that the ultrasonic beam is focused in a volume having a transverse dimension of less than 1 mm and preferably equal to or less than
0.5 mm.

25 7. The method as claimed in one or more of the preceding claims, characterized in that the ultrasonic beam is focused in a volume having a longitudinal dimension in the range from 1 to 8 mm and preferably in the range from 2 to 4 mm.

8. The method as claimed in one or more of the preceding claims,
30 characterized in that an acoustic coupling liquid is interposed between an ultrasonic transducer and the skin to be treated.

9. The method as claimed in claim 8, characterized in that said

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acoustic coupling liquid is placed in a transparent bag, said liquid also being transparent.

10. The method as claimed in one or more of the preceding claims, characterized by the steps of:

- 5 - using an optical aiming beam to orient an ultrasonic transducer toward an area of skin to be treated;
 - generating an ultrasonic acoustic beam by means of said transducer, focused under the skin surface of the area of skin to be treated.

11. The method as claimed in claim 10, characterized in that
10 the area of skin to be treated is observed through an optical magnifying means.

12. The method as claimed in one or more of the preceding claims, characterized in that the area of skin to be treated is superficially cooled.

15 13. The method as claimed in one or more of the preceding claims, characterized in that the ultrasonic beam has a frequency in the range from 100 kHz to 10 Mhz.

14. The method as claimed in one or more of the preceding claims, characterized in that said acoustic beam is a pulsed acoustic beam
20 having an acoustic energy per pulse in the range from 100 to 1200 mJ and preferably from 120 to 250 mJ.

15. The method as claimed in claim 14, characterized in that said pulses have a length in the range from 15 to 200 ms and preferably from 20 to 40 ms.

25 16. An epilation device characterized in that it comprises at least one generator of a focused ultrasonic beam.

17. The device as claimed in claim 16, characterized in that said focused ultrasonic beam has a power sufficient to cause the necrosis of the tissues struck by said beam.

30 18. The device as claimed in claim 16 or 17, characterized in that said generator comprises at least one intrinsically focused ultrasonic transducer.

- 15 -

19. The device as claimed in claim 16 or 17, characterized in that said ultrasonic generator comprises an array of ultrasonic transducers in the form of concentric rings.

5 20. The device as claimed in claim 16 or 17, characterized in that said ultrasonic generator comprises an ultrasonic transducer and focusing means.

21. The device as claimed in one or more of claims 16 to 20, characterized in that it comprises a handpiece on which said ultrasonic generator is located.

10 22. The device as claimed in claim 21, characterized in that said handpiece comprises a spacer element to keep said generator at the correct distance from the skin of a subject being given the epilation treatment, the focused zone of the acoustic beam being thus positioned in the volume of tissue underlying the skin surface and containing the hair follicle to be
15 removed.

23. The device as claimed in one or more of claims 16 to 22, characterized by a bag containing an acoustic coupling liquid.

24. The device as claimed in claim 23, characterized in that said bag and said acoustic coupling liquid are transparent.

20 25. The device as claimed in one or more of claims 16 to 24, characterized in that the ultrasonic generator generates a beam focused in a volume with a transverse dimension equal to or less than 1 mm and preferably equal to or less than 0.5 mm.

26. The device as claimed in one or more of claims 16 to 25, characterized in that the ultrasonic beam generator generates a beam
25 focused in a volume having a longitudinal dimension in the range from 1 to 8 mm and preferably in the range from 2 to 4 mm.

27. The device as claimed in one or more of claims 16 to 26, characterized in that it comprises an optical aiming system.

30 28. The device as claimed in claim 27, characterized in that said optical aiming system comprises a low-power laser source.

29. The device as claimed in one or more of claims 16 to 28,

- 16 -

characterized in that it comprises a system for magnifying the skin area to be treated.

30. The device as claimed in claim 29, characterized in that said magnifying system comprises a lens for the direct observation of the skin area to be treated.

31. The device as claimed in claim 29, characterized in that said magnifying system comprises a micro-video camera.

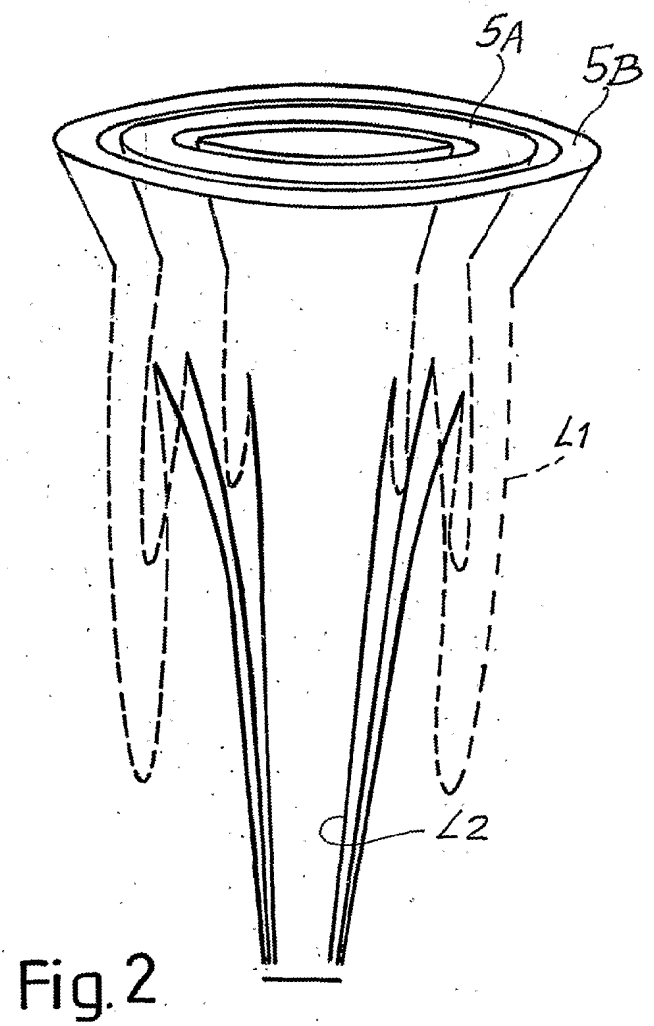
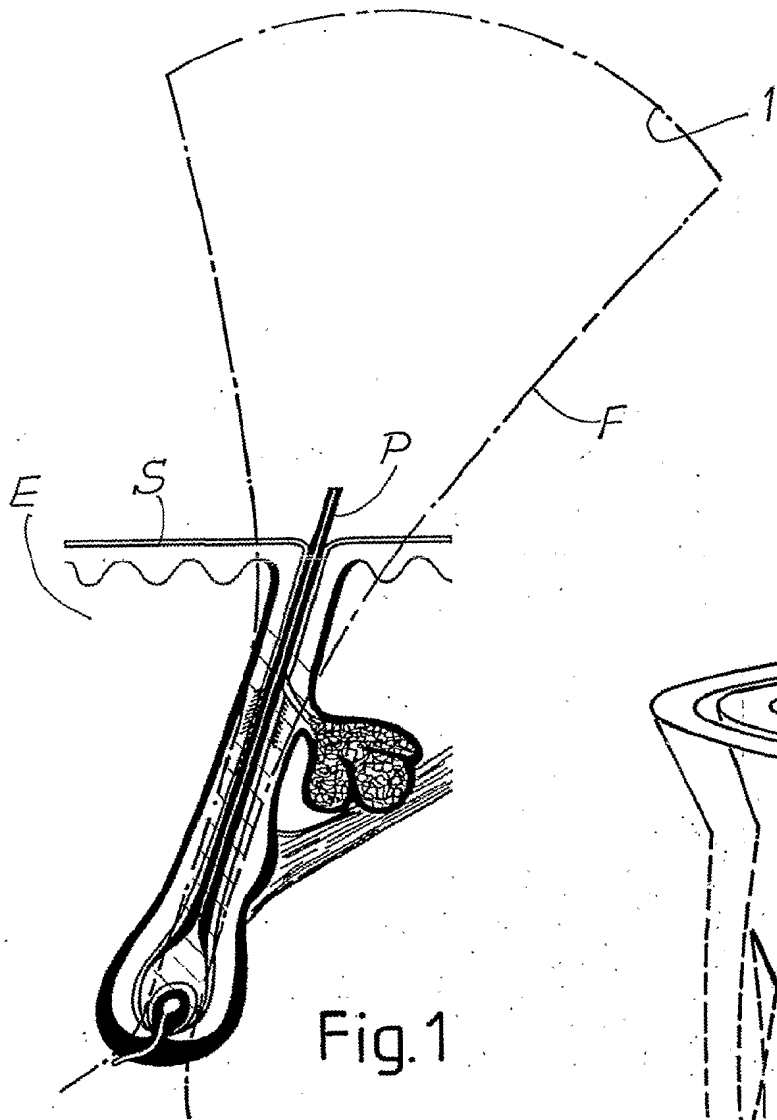
32. The device as claimed in one or more of claims 16 to 31, characterized in that it comprises a system for cooling the skin area to be treated.

33. The device as claimed in claims 22 and 32, characterized in that said cooling system comprises means for cooling said acoustic coupling liquid.

34. The device as claimed in one or more of claims 16 to 33, characterized in that said generator emits an acoustic beam with a frequency in the range from 100 kHz to 10 MHz.

35. The device as claimed in one or more of claims 16 to 34, characterized in that said generator emits a pulsed acoustic beam with an effective acoustic energy per pulse in the range from 100 to 1200 mJ and preferably from 120 to 250° mJ per pulse.

36. The device as claimed in claim 35, characterized in that said generator emits pulses with a length in the range from 15 to 200 ms and preferably from 20 to 40 ms.



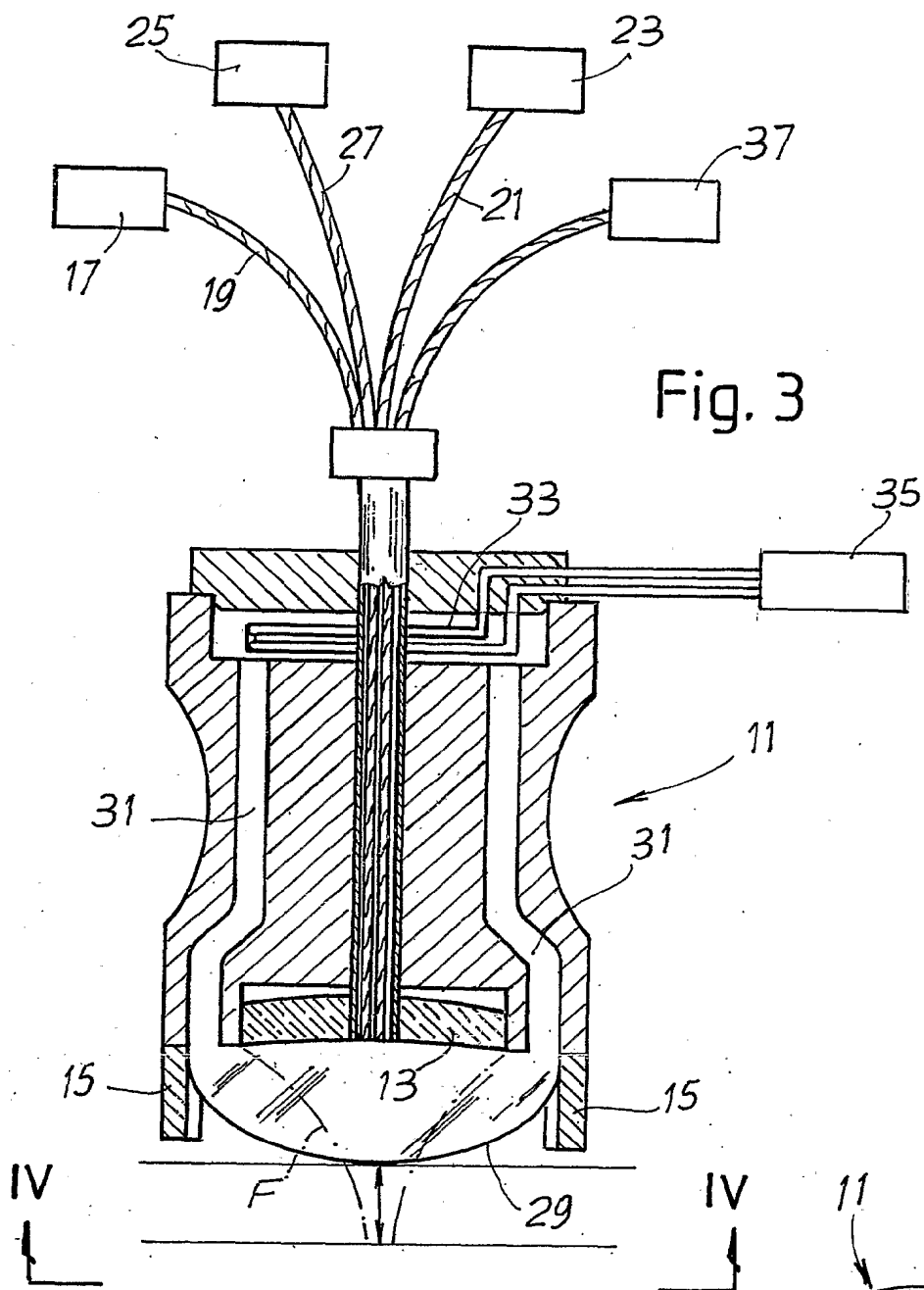
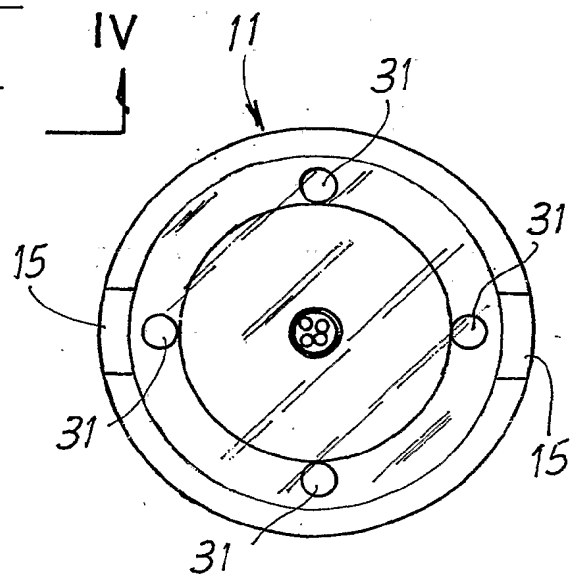


Fig. 4



INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N7/00

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 21612 A (IGER YONI ;SEGAL EMANUEL (IL); ELMAN DMITRY (IL); SHALHEVET DAVID) 20 April 2000 (2000-04-20)	1-8, 13-21, 25,26, 29,31, 34-36
Y	page 15, line 20 - line 27; figure 1; example 1	9,12, 22-24, 29,31-33
Y	US 4 556 070 A (MCEUEN ALBERT H ET AL) 3 December 1985 (1985-12-03) column 2, line 56 - line 61; figure 1	12,32,33
Y	US 4 646 756 A (HYNYNEN KULLEVRO ET AL) 3 March 1987 (1987-03-03) column 5, line 60 - line 62; figure 7	9,22-24
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IT 00/00324

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 860 967 A (EASTMAN JAY M ET AL) 19 January 1999 (1999-01-19)	29, 31
A	column 5, line 37 - line 47; figure 3	10, 11, 27, 28, 30
A	----- US 5 628 744 A (DAVENPORT SCOTT A ET AL) 13 May 1997 (1997-05-13) abstract; figure 6 -----	10, 11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IT 00/00324

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0021612 A	20-04-2000	AU 6119099 A	01-05-2000
US 4556070 A	03-12-1985	NONE	
US 4646756 A	03-03-1987	AT 30842 T DE 3374522 D EP 0111386 A	15-12-1987 23-12-1987 20-06-1984
US 5860967 A	19-01-1999	AU 7401094 A EP 0710136 A JP 9501334 T WO 9503089 A US 5653706 A	20-02-1995 08-05-1996 10-02-1997 02-02-1995 05-08-1997
US 5628744 A	13-05-1997	AU 1446595 A CA 2179600 A EP 0735841 A NZ 278275 A WO 9517130 A	10-07-1995 29-06-1995 09-10-1996 24-02-1997 29-06-1995

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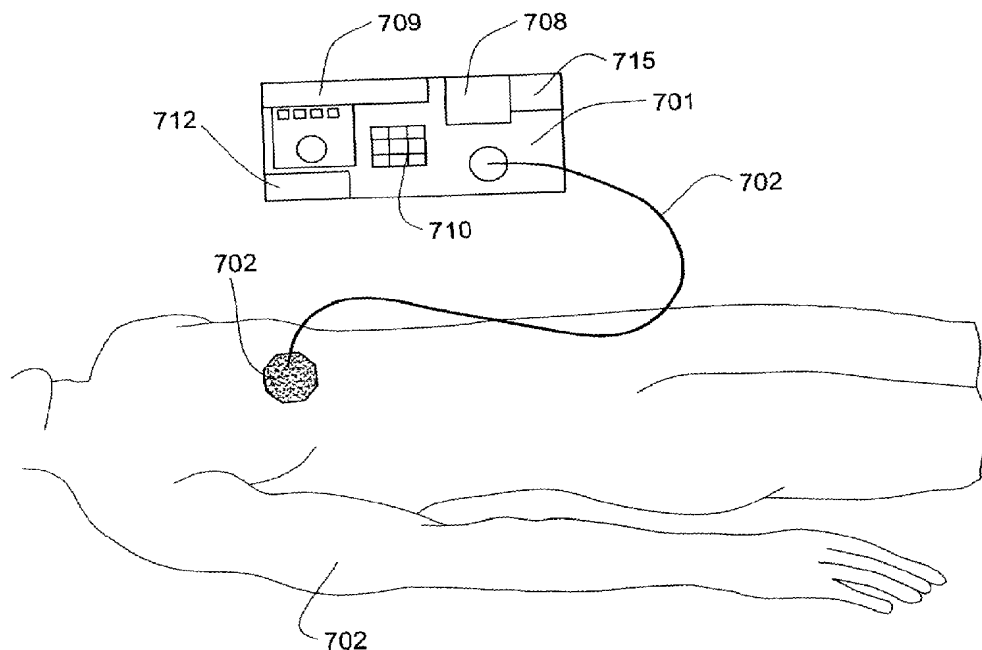
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[Continued on next page]

(54) Title: DEVICE AND METHOD FOR TREATING SKIN



(57) Abstract: A system and method for applying, essentially simultaneously, RF energy and optical energy to skin. The system comprises one or more RF electrodes for providing RF energy to the skin; and one or more light sources for providing optical energy to the skin. The method comprises applying, essentially simultaneously, RF energy and light energy to the skin. The method may be used for treating complex targets in the skin.



WO 02/26147 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE AND METHOD FOR TREATING SKIN

FIELD OF THE INVENTION

The invention relates to methods and devices for treating skin.

BACKGROUND OF THE INVENTION

The term "*complex target*" is used herein to refer to a feature of the skin
5 having a contrasted or pigmented, component, as well as an uncontrasted, or
unpigmented component. For example, a hair is a complex target in which the hair
shaft constitutes the contrasted component and the hair follicle constitutes the
uncontrasted component. A vascular lesion of the skin is another example of a
complex target in which blood constitutes the contrasted component and the walls
10 of the lesion the uncontrasted component. Improving the appearance of the skin
often involves the removal of unwanted complex targets.

Photothermolysis has been used for the removal of complex targets. In this
method, the target is illuminated with visible or infrared light that penetrates into
the target and is selectively absorbed by the contrasted component. The contrasted
15 component is thus heated, which in turn heats up the uncontrasted component. This
heating damages the two components of the target, which is ideally destroyed. U.S.
Patent No. 5,735,844 discloses removal of unwanted hairs using radiation having a
single wavelength in a pulse of 2 ms to 100 ms. U.S. Patent No. 5,683,380
discloses hair removal using incoherent filtered light. U.S. Patents Nos. 5,885,274,
20 5,964,749 and 5,810,801 disclose skin heating with coherent and non-coherent light
sources for smoothing skin and removing age-spots having wavelengths shorter
than 1.8 μ .

- 2 -

In order to be destroyed, the temperature of the target must be raised to about 70°C without raising the temperature of the epidermis to damaging levels. However, in many cases it is not possible by thermolysis to heat both components of the target to a temperature necessary for destroying the target without heating the surrounding skin to damaging levels. Fig. 1 shows the approximate temperature distribution around a hair after illuminating the hair with a short pulse of visible light. The theoretical curve shown in Fig. 1, as well as the curves shown in Figs. 2, and 5, referred to below, were obtained using a diffusion equation for light-tissue interactions, for example, as disclosed in Welch A.J. et al., Practical Models for light distribution in Laser-Irradiated tissue, in Lasers in Surgery and Medicine, 6:488-493, 1987, and using Maxwell equations for calculating RF current in tissue, for example, as disclosed in S. Gabriel, et al., The dielectric properties of biological tissues: III. Parametric models for dielectric spectrum of tissues. Phys. Med. Biol. 41: 2271-2293, 1996. Both of the aforementioned publications are incorporated herein by reference in their entirety. When the temperature of the shaft is over 65°C, the average temperature of the follicle is only about 55°. Thus, the optical energy absorbed by the hair shaft is insufficient to adequately heat the follicle. The temperature of the hair cannot be significantly raised beyond these temperatures without raising the temperature of the surrounding skin to damaging levels.

U.S. Patent No. 5,919,219 discloses using radio frequency (RF) energy for non-selective skin heating. In this method, RF energy is applied to the target that selectively heats the uncontrasted component. The uncontrasted component is thus heated, which in turn heats up the contrasted component. However in many cases, it is not possible using RF energy to heat both components of the target to a temperature necessary for destroying the target without heating the surrounding skin to damaging levels. Fig. 2 shows the approximate temperature distribution around a hair after a short pulse of RF energy. When the temperature of the follicle is over 55°C, the temperature of the shaft is only about 50°. The temperature in the skin surrounding the hair is around 40°. The temperature of the hair cannot be

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significantly raised beyond these temperatures without raising the temperature of the surrounding skin to damaging levels.

SUMMARY OF THE INVENTION

The present invention is based upon the unexpected finding that
5 simultaneous irradiation of a complex target with a combination of RF energy and light (optical energy) can simultaneously heat both the contrasted and uncontrasted components of complex target to a temperature that destroys both components without raising the surrounding skin temperature to damaging temperatures. Without wishing to be bound by a particular theory, it is believed that simultaneous
10 application of RF and optical energies decreases heat loss from the contrasted portion of a target that occurs with optical radiation alone, and similarly decreases heat loss from the uncontrasted portion of the target when RF energy is used alone.

The present invention thus provides a method and apparatus for dermatological treatment of complicated targets of skin in which RF and optical
15 energy are applied, essentially simultaneously, to the skin to heat a target within the skin. By "*essentially simultaneously*" is meant that the two forms of energy are applied simultaneously, or are applied in rapid succession to one another such that significant cooling of the target does not occur between the first and second applications of energy. The invention may be used for cosmetic treatment of any
20 complicated target such as hair removal, skin rejuvenation and vascular or pigmented lesions. The device includes an applicator with one or more electrode pairs for generation of RF energy and a light source emitting optical energy. Pulsed RF energy is applied by the electrodes applied to the skin either directly or through a conductive substance. The frequency of the RF is preferably at least 300 kHz in
25 order to prevent tissue spasms. The visible light may have a single wavelength or several wavelengths that are preferably selected to be optimal for the color of the contrasted component of the target, and are typically in the range of 500 to 1200 nm.

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Heat generation during the application of the RF and optical energies is higher near the skin surface. In order to make heating uniform within the skin, the surface is preferably cooled during treatment. The surface may be cooled by applying a cooled substance such as ice or ethanol to the skin or by using a thermoelectric cooler. The skin is preferably hydrated in order to enhance the penetration of the cooling into the deep layers of the skin, as is known in the art. When the skin is externally cooled at the surface, the RF and optical energy can heat the target to a depth of up to a few millimeters.

The RF electrodes may optionally be used to monitor skin impedance during the treatment. Since increasing skin temperature leads to a change in impedance, monitoring the skin impedance allows the temperature distribution in the skin to be followed so that the parameters of the treatment may be altered to optimize the treatment. The temperature distribution in the skin depends on the delay between the cooling and the application of the RF and optical energies, the selection of pulse parameters. The temperature distribution within the skin may thus be controlled by controlling the delay between the time the cooling is applied, and the time the RF and optical energy are applied. A microprocessor may be used for determining the optimal delay time (t) in response to a selected skin temperature profile. This may be calculated as is known in the art, for example, using the equation $t = d^2 / (4A)$, where d is the cooling depth, which in this case is about equal to the thickness of the epidermis (0.1 mm), and A is the skin diffusivity (about $1.4 \times 10^{-3} \text{ cm}^2/\text{sec}$). Alternatively or additionally, the temperature distribution may be controlled by controlling the pulse duration of the RF energy as is known in the art, for example, as disclosed in Ross et al., theoretical considerations in laser hair removal. IN Dermatologic Clinics, W.B. Saunders Company, Volume 17, pages 333-335, 1999.

The invention thus provides a system for applying, essentially simultaneously, RF energy and optical energy to skin comprising:

- (a) one or more RF electrodes adapted to provide RF energy to the skin;
- and

- 5 -

- (b) one or more light sources adapted to provide optical energy to the skin.

The invention also provides a method for treating skin comprising applying, essentially simultaneously, RF energy and light energy to the skin.

5 BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows the approximate temperature distribution around a 100 μm hair shaft and follicle following optical energy;

Fig. 2 shows the approximate temperature distribution around a 100 μm hair shaft and follicle following heating by RF;

Fig. 3 shows a system for simultaneously applying Rf and optical energy to an individual in accordance with the invention;

Fig. 4 shows an applicator with two electrodes, light source and cooling system; and

Fig. 5 shows temperature distribution around the 100 micron hair shaft created with combination of optical and RF energy.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to Fig. 3, a device for applying, essentially simultaneously, RF and optical energies in accordance with the invention is shown. An applicator **703**, to be described in detail below, contains a pair of RF electrodes and a light source. The applicator **703** is adapted to be applied to the skin of an individual **705** in the region of a complex target. The applicator **703** is connected to a control unit **701** via a cable **702**. The control unit **701** includes a power source **708**. The power source **708** is connected to an RF generator **715** that is connected to the RF electrodes in the applicator **703** via wires in the cable **702**. The power source **708** is also connected to the light source in the applicator **703** via

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wires in the cable **702**. The control unit **701** contains a refrigeration unit **712** that cools a fluid such as ethanol or water for cooling the applicator **703**. The cooled fluid flows from the refrigeration unit **712** to the applicator via a first tube in the cable **702**, and flows from the applicator **703** back to the refrigeration unit via a second tube in the cable **702**. The control unit **701** has an input device such as a keypad **710** that allows an operator to input selected values of parameters of the treatment, such as the frequency, pulse duration and intensity of the RF energy or the wavelength and intensity of the optical energy. The control unit **701** optionally contains a processor **709** for monitoring and controlling various functions of the device. For example, the processor **709** may monitor the electrical impedance between the electrodes in the applicator **703**, and determine the temperature distribution in the vicinity of the target. The processor **709** may also determine the parameters of the treatment based upon the impedance measurements.

Fig. 4 shows the applicator **703** in detail. The applicator contains a pair of electrodes **401** and **402** that apply RF energy to the skin. A light source **403** produces a light spectrum that is delivered to the skin surface by light guide **404**. The housing and electrodes are cooled by fluid cooled by the refrigeration unit **712** that flows in a tube **408** between inlet **405** and outlet **406**. The inlet **405** and the outlet **406** are connected to the refrigeration unit **712** via the first and second tubes in the cable **702**.

Using the system shown in Fig. 3 to apply RF and optical energies to a target having a diameter of at least 2 mm, the following exemplary parameter values may be used:

- Frequency of the RF energy: from about 300 kHz to about 100 MHz.
- Output power of the RF energy: from about 5 to about 200 W.
- Duration of the irradiation: from about 1 to about 500 msec.
- Pulse repetition rate: from about 0.1 to about 10 pulse per second.
- Intensity of the optical energy: from about 5 to about 100 Joules/cm².
- Pulse duration of optical energy: from about 1 to 200 msec.

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Fig. 5 shows the theoretical temperature distribution in a hair that is obtained using the system of Figs. 3 and 4 with these exemplary parameter values. The temperature in the hair shaft is over 85°C while the temperature in the surrounding skin is below 45°C.

CLAIMS:

1. A system for applying, essentially simultaneously, RF energy and optical energy to skin comprising:
 - (a) one or more RF electrodes adapted to provide RF energy to the skin; and
 - 5 (b) one or more light sources adapted to provide optical energy to the skin.
2. The system according to Claim 1 further comprising a cooling unit adapted to cool the skin.
3. The system according to Claim 2 wherein the cooling unit comprises a refrigeration unit cooling a fluid and tubes for allowing the fluid to flow near the
10 skin.
4. The system according to Claim 2 wherein the cooling unit comprises a thermoelectric cooler.
5. The system according to Claim 1 further comprising a impedance meter for measuring an impedance across one or more of the RF electrode pairs.
- 15 6. The system according to Claim 5 further comprising a processor configured to determine a heat distribution in the skin based upon one or more impedance measurements.
7. The system according to Claim 6 wherein the processor is further configured to determine one or more parameters of the RF energy based upon one or more
20 impedance measurements.
8. The system according to Claim 7 wherein the one or more parameters are selected from the group comprising a pulse duration of the RF energy, a frequency of the RF energy, a power of the RF energy, and a delay time between cooling the skin an application of the RF energy.
- 25 9. The system according to Claim 1 further comprising input means for determining one or more parameters of the RF energy or the optical energy.
10. The system according to Claim 9 wherein the one or more parameters are selected from the group comprising a pulse duration of the RF energy, a frequency of the RF energy, a power of the RF energy, a delay time between cooling the skin

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and application of the RF energy, one or more wavelengths of the optical energy, and an intensity of the optical energy.

11. A method for treating skin comprising applying, essentially simultaneously, RF energy and light energy to the skin.

5 **12.** The method according to Claim 11 further comprising cooling the skin.

13. The method according to Claim 12 wherein cooling the skin involves cooling a fluid and allowing the fluid to flow near the skin.

14. The method according to Claim 12 wherein cooling the skin comprises involves a thermoelectric cooler.

10 **15.** The method according to Claim 11 further comprising measuring an impedance across one or more RF electrode pairs.

16. The method according to Claim 15 further comprising determining a heat distribution in the skin based upon one or more impedance measurements.

17. The method according to Claim 16 further comprising determining one or
15 more parameters of the RF energy based upon one or more impedance measurements.

18. The method according to Claim 17 wherein the one or more parameters are selected from the group comprising a pulse duration of the RF energy, a frequency of the RF energy, a power of the RF energy, a delay time between cooling the skin
20 an application of the RF energy, one or more wavelengths of the optical energy, and an intensity of the optical energy.

19. The method according to Claim 11 wherein a frequency of the RF energy is from about 300 kHz to about 100 MHz.

20. The method according to Claim 11 wherein a duration of the RF radiation or
25 the optical radiation is from about 1 to about 500 msec.

21. The method according to Claim 11 wherein an output power of the RF energy is from about 5 to about 200 W.

22. The method according to Claim 11 wherein a pulse repetition rate is from about 0.1 to about 10 pulses per second.

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23. The method according to Claim 11 wherein an intensity of the optical energy is from about 5 to about 100 Joules/cm².

24. The method according to Claim 11 wherein a pulse duration of optical energy is from about 1 to 200 msec.

5 **25.** The method according to Claim 11 further comprising hydrating the skin.

26. The method according to Claim 11 for use in destroying a complex target in the skin.

27. The method according to Claim 26 wherein the complex target is selected from the group comprising a hair and a vascular lesion.

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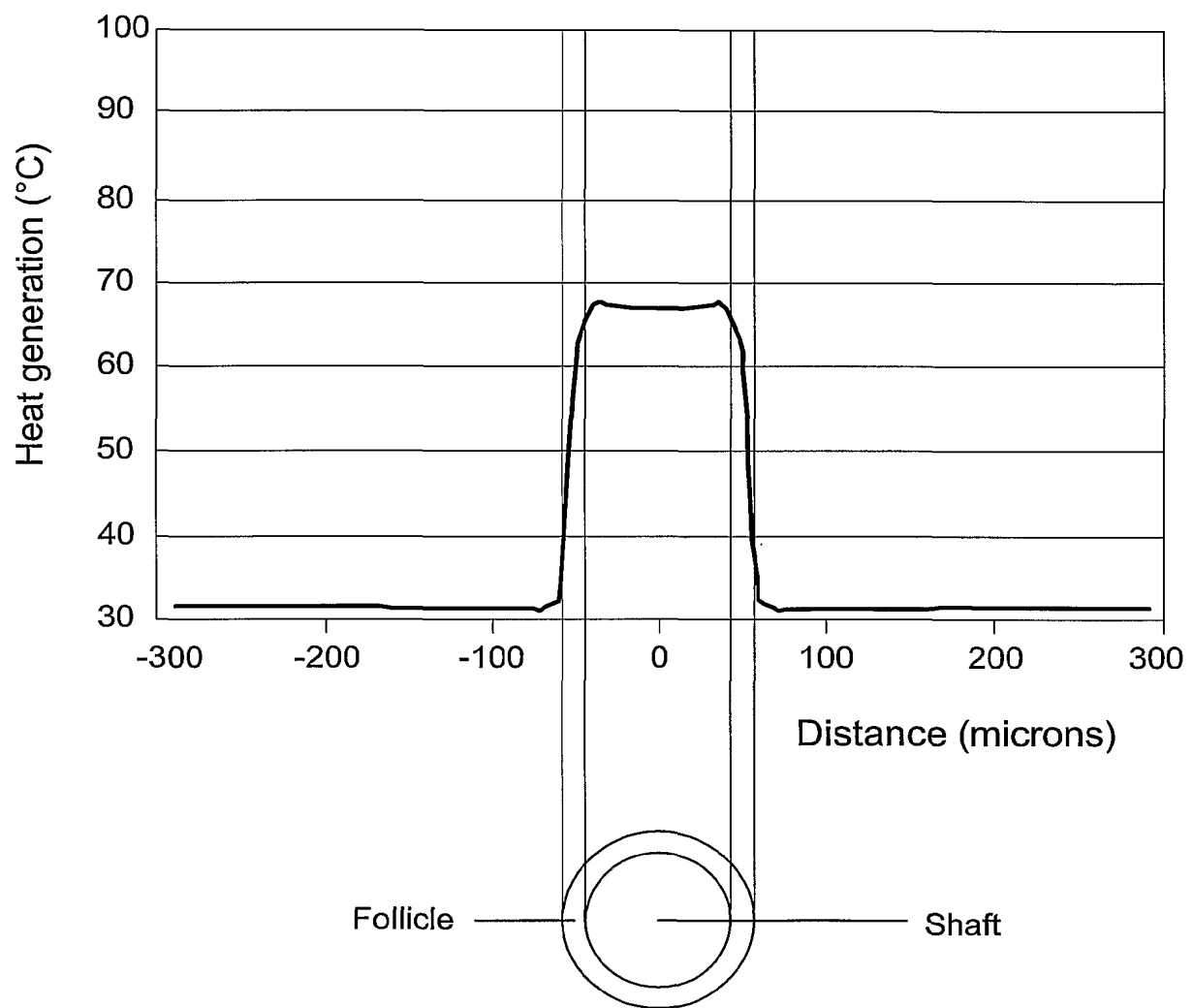


FIG. 1
(PRIOR ART)

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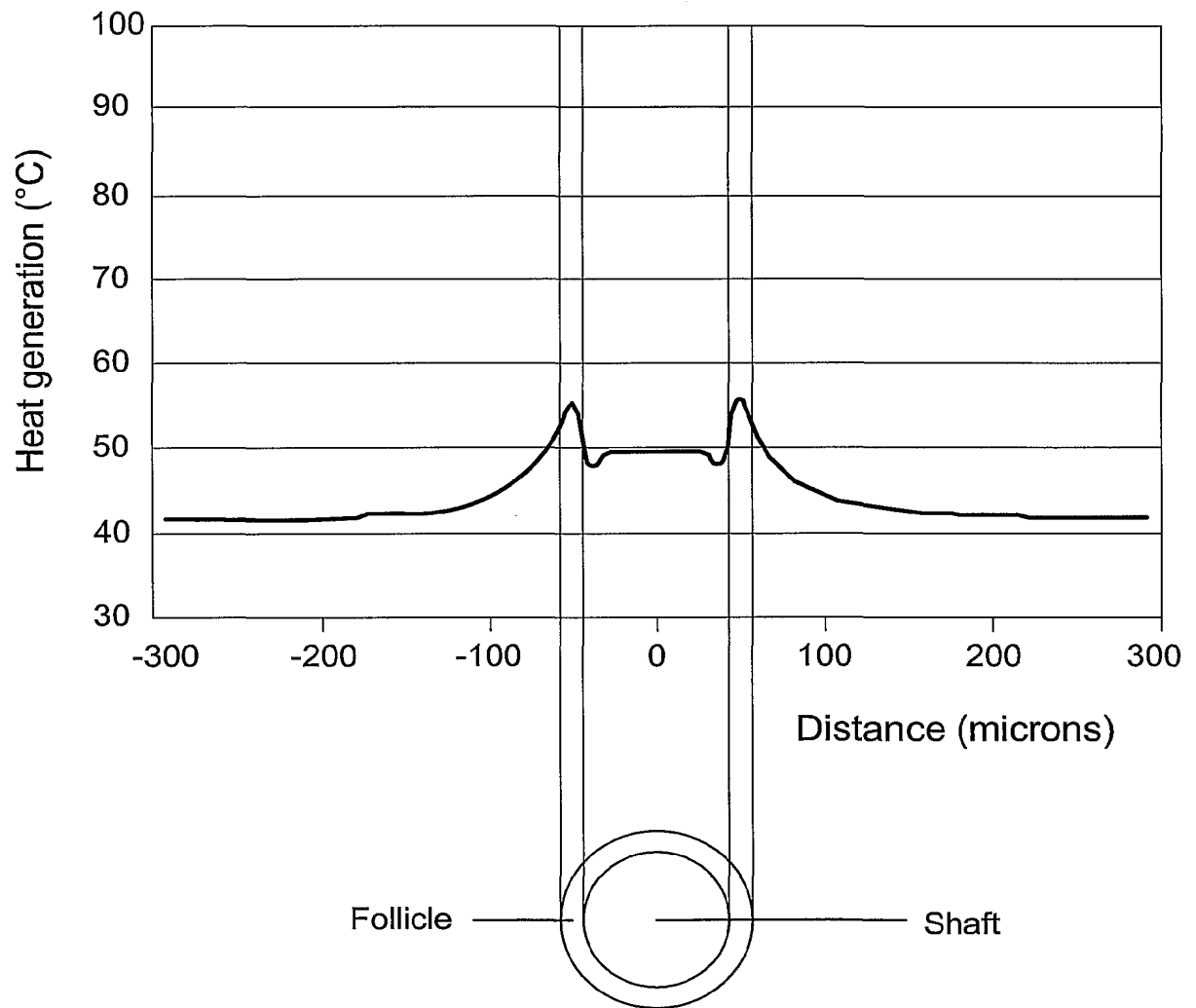


FIG. 2
(PRIOR ART)

3/5

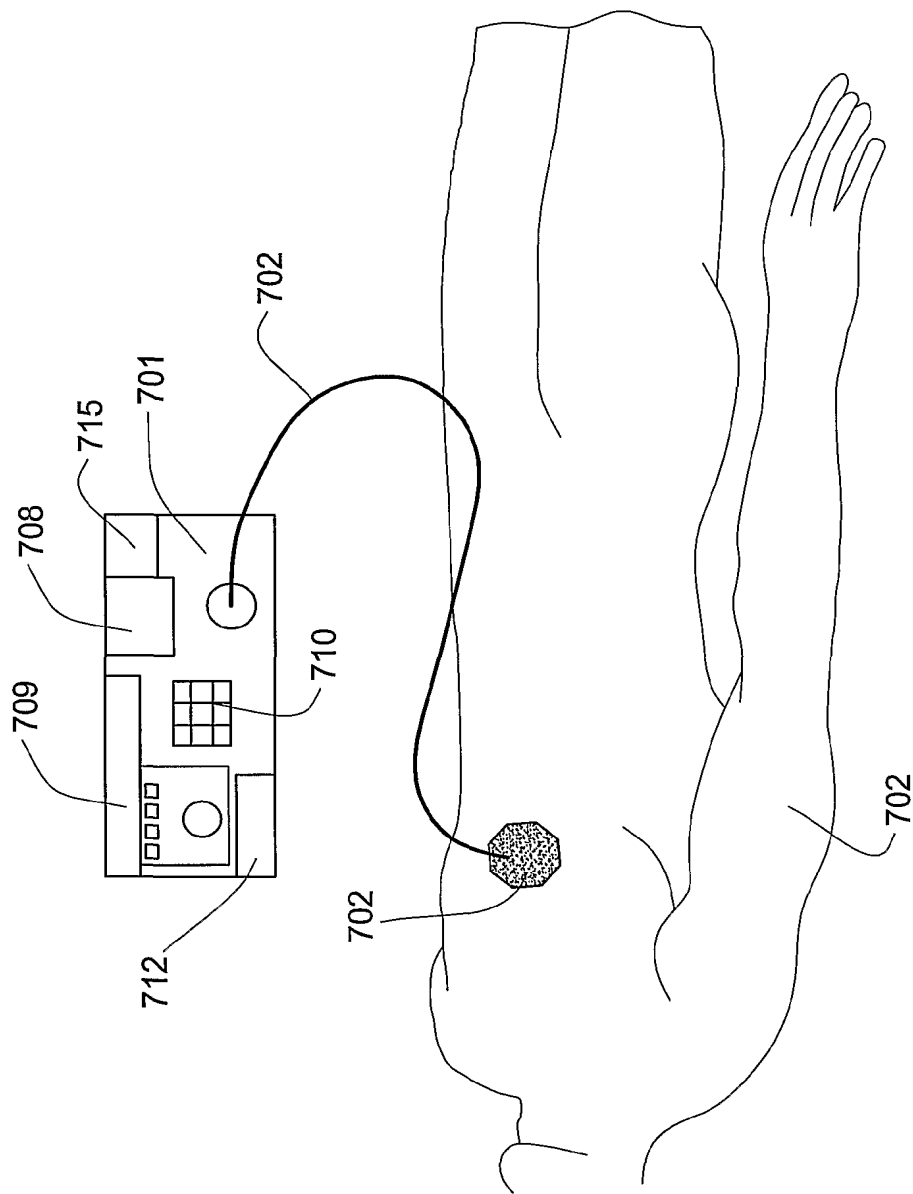


FIG. 3

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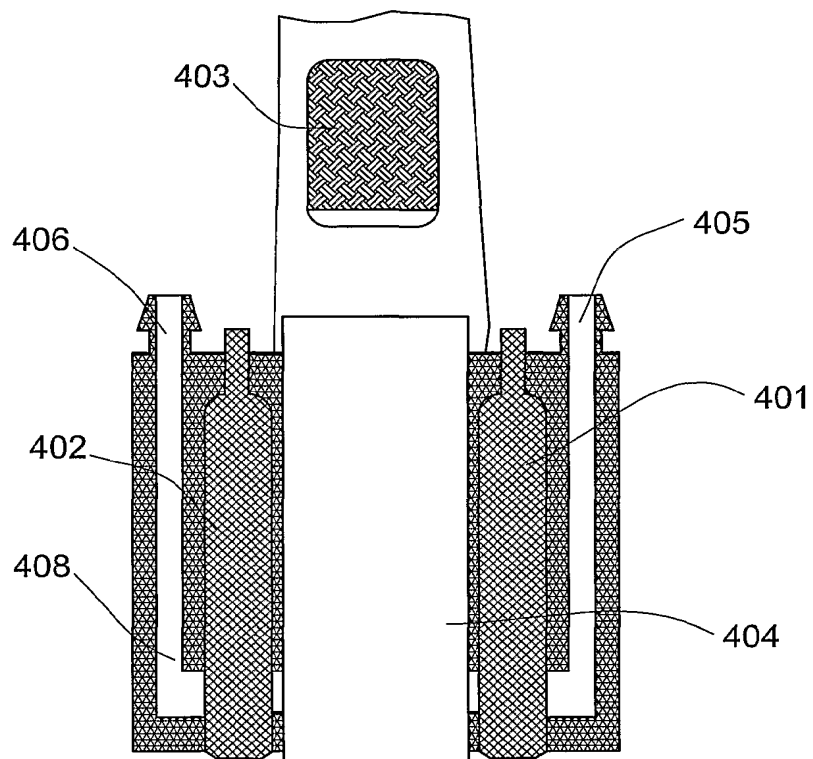


FIG. 4

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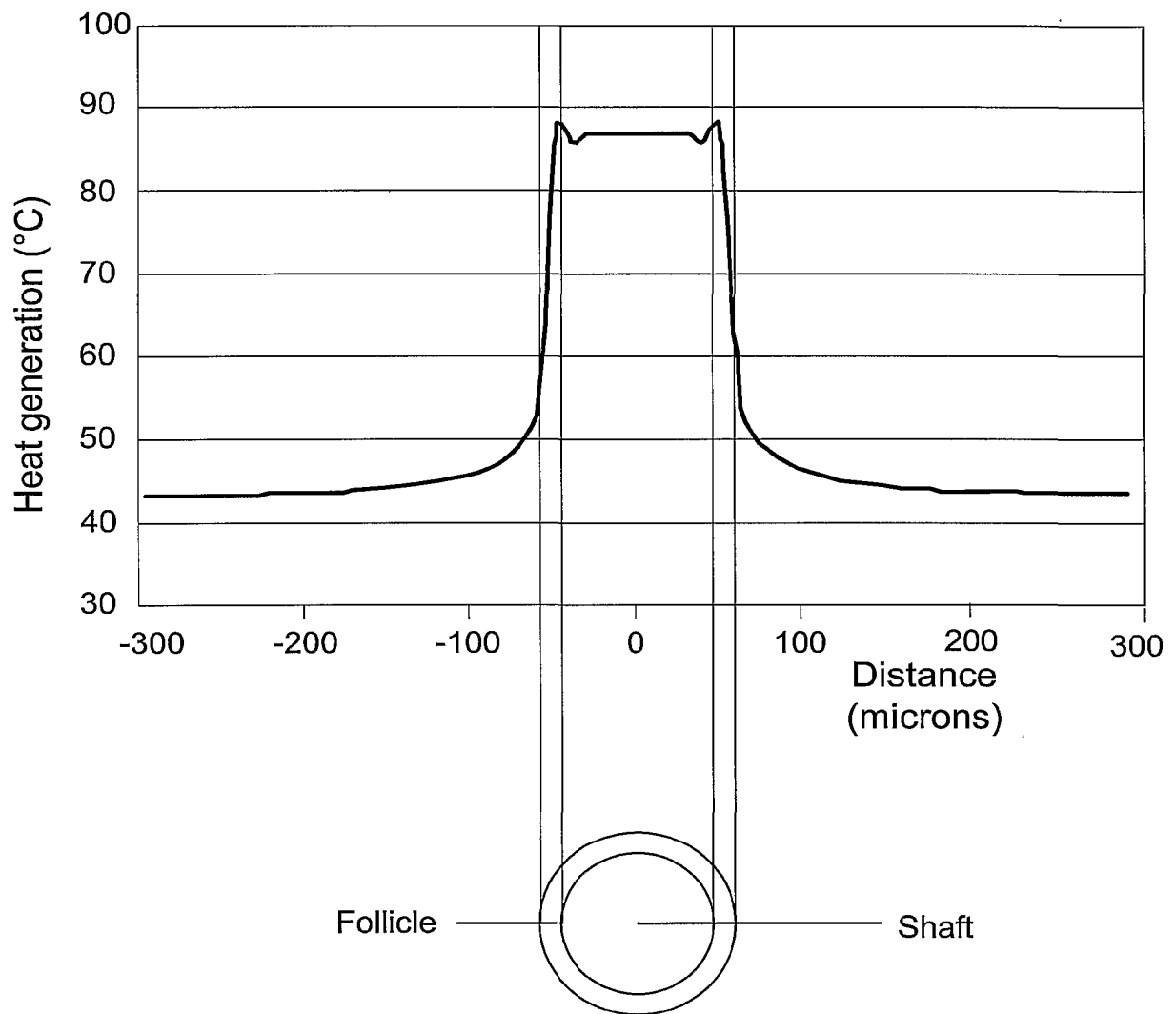


FIG. 5

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

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B. FIELDS SEARCHED

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IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 090 101 A (QUON DAVID K ET AL) 18 July 2000 (2000-07-18)	
A	US 5 906 609 A (ASSA SHLOMO ET AL) 25 May 1999 (1999-05-25)	

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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6090101	A	18-07-2000	AU 1909299 A WO 9929245 A1	28-06-1999 17-06-1999
US 5906609	A	25-05-1999	NONE	